EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2011 update)

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SCIENTIFIC OPINION

Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2011 update)[1]

EFSA on Biological Hazards (BIOHAZ)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

EFSA is requested to assess the safety of a broad range of biological agents (including microorganisms and viruses) in the context of notifications for market authorisation as sources of food and feed additives, enzymes and plant protection products. The qualified presumption of safety (QPS) assessment was developed by EFSA for its own use to provide a generic risk assessment approach applicable across EFSA's scientific Panels, for biological agents notified for intentional use in the whole food chain. The safety of unambiguously defined biological agents at the highest taxonomic unit that is appropriate for the purpose for which an application is intended and the completeness of the body of knowledge are assessed. Identified safety concerns for a taxonomic unit are where sensible reflected as 'qualifications' when a recommendation for the QPS list is given. The list of QPS recommended biological agents is reviewed and updated annually. Therefore, the only valid list is the one in the most recent scientific opinion. The 2011 update reviews microorganisms previously assessed including bacteria, yeasts, filamentous fungi and viruses used for plant protection purposes and confirms the previous recommendations. The anamorph yeast form *Phaffia rhodozyma* of *Xanthophyllomyces dendrorhous* was included on the QPS list and to the qualification for yeasts 'absence of resistance to antimycotics used for medical treatment of yeast infections', the sentence was added that 'in the case of *Saccharomyces cerevisiae* this qualification applies for yeast strains able to grow above 37 °C'. The body of knowledge of filamentous fungi and enterococci was updated and their ineligibility for the QPS list confirmed.

KEY WORDS

Safety, QPS, bacteria, yeast, fungi, virus

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[1] On request from EFSA, Question No EFSA-Q-2011-00070, adopted on 7 December 2011.

[2] Panel members: John Daniel Collins, Birgit Noerrung, Herbert Budka, Olivier Andreoletti, Sava Buncic, John Griffin, Tine Hald, Arie Havelaar, James Hope, Günter Klein, James McLauchlin, Christine Müller-Graf, Kostas Koutsoumanis, Christophe Nguyen-The, Luisa Peixe, Miguel Prieto Maradona, Antonia Ricci, John Sofos, John Threlfall, Ivar Vågsholm and Emmanuel Vanopdenbosch. Correspondence: biohaz@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on the maintenance of the list of QPS biological agents intentionally added to food or feed (2011 update): Pier Sandro Cocconcelli, Florence Richard Forget, Günter Klein, Tine Licht, Peixe Luisa, Christophe Nguyen-The, Amparo Querol, Ulf Thrane, Just M. Vlak and Atte von Wright for the preparatory work on this scientific opinion and, the hearing expert: Malcolm Richardson, and EFSA staff: Renata Leuschner for the support provided to this scientific opinion.

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SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on the maintenance of the list of QPS biological agents (microorganisms and viruses) intentionally added to food or feed (2011 update). The question included five specific tasks.

The first required the preparation of an update of the list of biological agents notified to EFSA for safety assessment. This should be a starting point for identifying new taxonomic units for review under the QPS assessment. Only those taxonomic units relevant to current legal requirements in the context of notification to EFSA for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products shall be included. The list was updated with the notifications received where applicable by EFSA Panels and Units since the last review.

The second aspect was concerned with an annual review of the list of biological agents recommended for the QPS list. Where appropriate new taxonomic units should be assessed for their suitability for an inclusion in the QPS list, and taxonomic units previously assessed should be reviewed where new information has become available. The information provided in the previous opinion should be updated where appropriate.

The BIOHAZ Panel confirmed all taxonomic units previously recommended for the QPS list. The information of the previous opinion was updated for the taxonomic units on the QPS list. The notifications were assessed and no new recommendations for the QPS list were made.

An assessment of three new bacterial species (*Ensifer adhaerens* and *Ensifer fredii*, *Ketogulonicigenium vulgare*, *Clostridium butyricum*), a new yeast species (*Trichosporon mycotoxinivorans*) and several additional fungi species (*Ampelomyces quisqualis*, *Ashbya gossypii*, *Aspergillus aculeatus*, *Trichoderma asperellum*, *Trichoderma longibrachiatum* for enzyme production, *Trichoderma viride* for enzyme production) was performed but these species were not included on the QPS list.

Phaffia rhodozyma the imperfect form of *Xanthophyllomyces dendrorhous* was included on the QPS recommended list. In accordance with the most recent taxonomic revision of yeasts, the new name of *Pichia jadinii* was changed to *Lindnera jadinii*.

Tasks three and four required, for the taxonomic units included in the QPS recommended list, a review and update of knowledge concerning antimicrobial resistance and a review of the qualifications. The information of the previous opinion was updated by the BIOHAZ Panel for bacteria and the qualification on antimicrobial resistance was confirmed.

For the yeast the knowledge on antimycotic resistance was updated and the qualification ‘on absence of resistance to antimycotics used for medical treatment of yeast infections’ was complemented by the sentence ‘in the case of *Saccharomyces cerevisiae* this qualification applies for yeast strains able to grow above 37 °C’. This qualification is only relevant if viable yeasts are intentionally introduced into the food chain and it was restricted to those yeast species for which information on antifungal susceptibility exists.

The final aspect included a review of the body of knowledge for filamentous fungi and enterococci. The BIOHAZ Panel updated the knowledge of filamentous fungi notified for EFSA. Although numerous data, published since the 2010 QPS opinion, have contributed to partially fulfil gaps of knowledge, too many unknowns remain in 2011 to allow a filamentous fungus to be qualified as QPS. Enterococci cannot be considered for the QPS list based on the current scientific knowledge.

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BACKGROUND AS PROVIDED BY EFSA

A wide variety of bacterial and fungal species are used in food and feed production, either directly or as a source of additives or food enzymes. Some of these have a long history of apparent safe use, while others are less well understood and may represent a risk for consumers. Experience has shown that there is a need for a tool for setting priorities within the risk assessment of those microorganisms used in the production of food/feed which are captured by present legislation and consequently the subject of a formal safety assessment.

In 2002/3 a working group consisting of members of the former Scientific Committees on Animal Nutrition, Food and Plants of the European Commission proposed the introduction for selected microorganisms of a Qualified Presumption of Safety (QPS)[4].

In April 2003, responsibility for the safety assessments of food/feed undertaken by the Scientific Committees of the Commission formally passed to the European Food Safety Authority (EFSA). Shortly after EFSA asked its own Scientific Committee to consider whether the approach to safety assessment of microorganisms proposed in the QPS document could be used to harmonise approaches to the safety assessment of microorganisms across the various EFSA scientific panels.

The Scientific Committee concluded that QPS as a concept could provide a generic approval system *for use within EFSA* that could be applied to all requests received for the safety assessments of microorganisms deliberately introduced into the food chain[5]. The benefits of the introduction of QPS would be a more transparent and consistent approach across the EFSA panels and the potential to make better use of resources by focussing on those organisms which presented the greatest risks or uncertainties. The Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA Opinion and published a list of microorganisms recommended for QPS[6].

The Scientific Committee recommended that a QPS approach should be implemented across EFSA and applied equally to all safety considerations of microorganisms that EFSA is required to assess. In reaching its conclusion on the value of QPS as an assessment tool, the Scientific Committee recognised that there would have to be continuing provision for reviewing and modifying the list of organism given QPS recommendation. They recommended that the EFSA via its Panel on Biological Hazards (BIOHAZ) should take prime responsibility for this and should review the existing QPS list and any additions at least annually. Reviews may occur more frequently as necessary but there should be a formal requirement that even when no changes are proposed, a statement should be made annually that QPS recommendation is being maintained for the published list.

4 See http://ec.europa.eu/food/fs/sc/scf/out178_en.pdf
5 See www.efsa.europa.eu/en/science/sc_commitee/sc_opinions/972.html
6 See www.efsa.europa.eu/en/scdocs/scdoc/587.htm

In the first annual QPS review and update[7], the existing list of QPS microorganisms was reviewed and EFSA's initial experience in applying the QPS approach was described. In addition, following the identification of antimicrobial resistance as a universal qualification of safety in the previous Opinions on QPS, the issue was addressed in line with the opinion developed by the BIOHAZ Panel[8] on 'Foodborne antimicrobial resistance as a biological hazard', and related documents[9,10,11] of other EFSA Panels. The potential application of the QPS approach to microbial plant protection products was discussed in the most recent reviews [12,13].

The 2009 update[9] reviews the previously assessed microorganisms including bacteria, yeasts and filamentous fungi and assesses several additional notifications concerning gram-positive and gram-negative bacteria and yeasts. *Lactobacillus cellobiosus*, *Lactobacillus collinoides*, *Propionibacterium acidopropionici* and *Oenococcus oeni* were included in the QPS list. No filamentous fungi were included because of potential production of toxic metabolites in line with previous QPS assessments[3]. For the first time viruses were assessed. Insect viruses (Baculovirideae) and in the case of zucchini yellow mosaic viruses the Potyvirideae family as the highest possible taxonomic unit were added to the QPS list. Bacteriophages were considered as not appropriate for the QPS list. A potential presence of antimycotic resistance of yeasts referred to on the QPS list was considered. It was concluded that yeast strains resistant to antimycotics used for treatment of infections in humans might be of public health concern.

In the last QPS update in 2010[13] the previously assessed microorganisms including bacteria, yeasts, filamentous fungi and viruses used for plant protection purposes were reviewed and the QPS recommendations of the previous year were confirmed. Qualifications, intended to exclude potential safety concerns, relating to the agents recommended for the QPS list were also reviewed, clarified and updated where necessary. Specific sections dealing with antibiotic resistance relevant for QPS recommended microorganisms were included. The methodology used for carrying out the annual review of the list of QPS recommended biological agents was detailed. A list of microbial species from previous notifications and as notified to EFSA, annexed in this opinion, included information on taxonomic units which are or are not recommended for the QPS list with the rational for this decision. This list of notifications aims to summarize and maintain important information for future assessments and updates and is intended to be updated annually.

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7 Opinion of the Scientific Panel on Biological Hazards on a request from EFSA on the maintenance of the list of QPS microorganisms intentionally added to food or feed. The EFSA Journal (2008) 923, 1-48.

8 Opinion of the Scientific Panel on Biological Hazards on a request from EFSA on foodborne antimicrobial resistance as a biological hazard. The EFSA Journal (2008) 765, 1-87.

9 Technical guidance prepared by the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on the update of the criteria used in the assessment of bacterial resistance to antibiotics of human or veterinary importance. The EFSA Journal (2008) 732, 1-15.

10 Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Microorganisms and their Derived Products Intended for Food and Feed Use. The EFSA Journal (2006) 374, 1-115.

11 EFSA, 2010. Public consultation on: "Guidance on the risk assessment of genetically modified microorganisms and their food and feed products". Published on EFSA's website: 29 November, 2010; deadline: 24 January, 2011. www.efsa.europa.eu/en/consultations/call/gmo101129.htm

12 Scientific Opinion of the Panel on Biological Hazards (BIOHAZ) on the maintenance of the list of QPS microorganisms intentionally added to food or feed (2009 update). The EFSA Journal (2009), 7(12): 1431

13 Scientific Opinion of the Panel on Biological Hazards (BIOHAZ) on the maintenance of the list of QPS biological agents intentionally added to food or feed (2010 update). EFSA Journal 2010; 8(12):1944

TERMS OF REFERENCE AS PROVIDED BY EFSA

EFSA requests the BIOHAZ Panel to:

1. Preparation of an update of the list of biological agents notified to EFSA for safety assessment. This should be a starting point for identifying new taxonomic units for review under the QPS assessment. Only those taxonomic units relevant to current legal requirements in the context of notification to EFSA for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products shall be included.

2. Annual review of the list of biological agents recommended for the QPS list. Where appropriate new taxonomic units should be assessed for their suitability for an inclusion on the QPS list, and taxonomic units previously assessed should be reviewed where new information has become available. The information provided in the previous opinion should be updated where appropriate.

3. Review and update of knowledge concerning antimicrobial resistance in taxonomic units recommended for the QPS list.

4. Review of the qualifications for taxonomic units included in the QPS recommended list.

5. Review of the body of knowledge for filamentous fungi and enterococci.

ASSESSMENT

1. Introduction

A wide variety of microorganisms are intentionally added at different stages into the food chain, either directly or as a source of additives or enzymes. In this context, approximately 100 species of microorganisms have been expected to be referred to EFSA for a safety assessment. The majority are the result of notifications for market authorisation as sources of food and feed additives, food enzymes and plant protection products received by EFSA.

The purpose of the present Opinion is to review the list of previously Qualified Presumption of Safety (QPS) recommended biological agents which was last established in 2010 (EFSA, 2010). The QPS approach was developed by the Scientific Committee to provide a generic concept to prioritise and to harmonise risk assessment of microorganisms intentionally introduced into the food chain within EFSA in support of the respective Scientific Panels and Units in the frame of authorisations (EFSA, 2007). The list, first established in 2007 is to be reviewed annually (EFSA, 2007). Taxonomic units were included in the QPS list either following notifications to EFSA or following proposals made during a public consultation in 2005 by stakeholders, even if they were not yet notified to EFSA (EFSA, 2005).

1.1. QPS an assessment approach for use within EFSA

QPS as a concept could provide a generic approval system for use within EFSA that could be applied to all requests received by EFSA for the safety assessments of microorganisms deliberately introduced into the food chain. Its introduction would make the risk assessment approach more transparent across the EFSA Scientific Panels and Units. It would aid the consistency of assessment and make better use of resources by focussing on those organisms which present the greatest risks or uncertainties (EFSA, 2005).

In the QPS concept a safety assessment of a defined taxonomic unit is considered independently of any particular specific notification in the course of an authorisation process. If the taxonomic unit does not raise any safety concerns, or if existing safety concerns can be clearly defined as specific qualifications to ensure their absence (exclusion) in the context of a specific notification, a particular taxonomic unit could be recommended for the QPS list. Subsequently, any specific representative of a QPS proposed taxonomic unit, would not need to undergo a further safety assessment other than to satisfy any of the qualifications specified if applicable. Representatives of groups that fail to satisfy a qualification would be considered unfit for the QPS list and would remain subject to a full safety assessment, in the frame of a notification within the responsible EFSA Scientific Panel (EFSA, 2007).

The QPS concept does not address hazards linked to the formulation or processing of the products based on biological agents added into the food or feed chain. These aspects are assessed, where applicable, separately by the EFSA Panel responsible for assessing the notification.

Concerning microorganisms discussed in previous Opinions, the continuously evolving body of knowledge possibly reveals new information that could lead to a modification of the list of QPS recommended taxonomic units, for example to an ex- or inclusion of taxonomic units on the list. An assessment of taxonomic units, not previously considered for the QPS list, and for which representatives are notified to EFSA is also discussed. These include, beside microorganisms, viruses used in the context of plant protection and bacteriophages. Consequently, the QPS 2011 update will review these biological agents. Biological agents intended for usages outside the remit of EFSA, and biological agents which have not been notified to EFSA, are not considered in this Opinion.

In 2008 antimicrobial resistance was introduced as a possible safety concern for the assessment of the inclusion of bacterial species in the QPS list (EFSA, 2008a). In the 2009 and 2010 Opinions (EFSA, 2009, 2010) a qualification regarding absence of antimycotic resistance for yeast was introduced. The qualifications are reviewed and discussed in the present Opinion.

In accordance with the recommendation by the Scientific Committee that the QPS concept should be implemented within EFSA where relevant, an impact assessment of the QPS system by EFSA Units in the frame of authorisations and its quotation in the scientific literature is provided.

1.2. Experience of using the QPS approach within EFSA

The QPS approach has proved to be a useful tool to harmonise and prioritise safety assessment within EFSA and is appreciated by both assessors and applicants. The QPS recommended list was mainly used by the EFSA's Panel on Additives and Products of Substances used in Animal Feed (FEEDAP). If a biological agent is recommended for the QPS list this covers in their assessment as well safety for consumers, animals and the environment. Neither safety of users handling the product nor genetic modifications are taken into account. In the respective FEEDAP Opinions dealing with QPS recommended microorganisms a standard sentence is included that the active agent in question is considered by the European Food Safety Authority (EFSA) to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment. Therefore, no assessment of safety for the target species, consumer and the environment is required. Until 7th October 2011, the QPS approach has been applied by FEEDAP, in the assessment of 20 dossiers out of a total of 22 published opinions concerned with a safety assessment of microorganisms as feed additives (EFSA, 2011a-t).

The annual QPS updates provide relevant new information from the literature for biological agents currently under peer-review which, if showing more critical or adverse effects, will be taken into account during the process of the peer-review or in the EFSA conclusion. When a microorganism is approved under Regulation (EC) No 1107/2009 (Official Journal of the European Union, 2009), a cycle of 10 to 15 years is foreseen for the revision of the dossier including new information according to the regulatory framework. This shows the usefulness of the QPS approach as a mean of regularly updating the body of knowledge on taxonomic units of importance for EFSA Panels and Units, even if they are not on the QPS list. Hence, the annual update of the body of knowledge concerning fungi is appreciated by the Pesticide Unit.

Biological agents recommended for the QPS list and proposed as plant protection products (under the Directive 91/414/EC (Official Journal, 1991) could be exempt from certain data requirements such as oral toxicity data. However, the QPS recommendation does not address other risks, specifically risks for the user and risks for the environment, which have to be assessed specifically for plant protection products according to the Regulation (EC) No 1107/2009 (Official Journal of the European Union, 2009). The activity of maintenance of the QPS list has also been communicated to the Pesticide Steering Committee in March 2011.

1.3. Reference to QPS in the scientific literature

Since the publication of the EFSA 2010 Opinion (EFSA, 2010) which cited and discussed references to the QPS approach in the scientific literature, additional references were made to the concept. Those published by the end of July 2011 were collected. Some publications refer to documents which seem to make reference to other documents than those published by EFSA (Delorme et al., 2010; Forssten et al., 2011a; b; Izawa et al., 2011;), others refer to initial QPS documents published by EFSA (reports and opinion up to 2007) rather than to the recently updated QPS opinions (Aureli et al., 2011; Ayeni et al., 2011; Cintas et al., 2011; Doyle and Erickson, 2011; Engel et al., 2011; Kneifel, 2011; Mayrhofer et al., 2011; Moslehi-Jenabian et al., 2010; Salazar et al., 2011; Saxelin et al., 2011; Seitter et al., 2011; Talon and Leroy, 2011) while some refer to more recent QPS opinions as of 2008

(Chanos and Williams, 2011; Chenoll et al., 2010; Clementi and Aquilanti, 2011; Cousin et al., 2011; Ferreira et al., 2011; Johnsson Holmsberg, 2011; Klein, 2011a; Meieregger et al., 2011; Ouwehand et al., 2011; Patel et al., 2010; Sundh and Melin, 2011).

The list of QPS recommended biological agents is reviewed and updated annually therefore the only valid list is the one from the most recent scientific opinion.

Other publications appear to mention the QPS assessment without any reference (Sanders and Levy, 2011; Schroeder et al., 2011; Xu et al., 2011) and some of these seem to suggest a change of QPS recommendations such as for example for *Streptococcus thermophilus* (La Gioia et al., 2011). Fjelsted and Ehlers (2011) specifically discuss the QPS approach as a tool to support the registration process of biological control agents used in agriculture. It should be noted that the QPS approach is used for risk assessment only within EFSA.

Few publications refer to the QPS assessment in analogy with the Generally Recognised As Safe (GRAS) concept used in the United States (Ladero et al., 2011; Pilet and Leroi, 2011; Zago et al., 2011) and it has to be clearly emphasised in that the QPS assessment is different in its overall aim and use.

2. Methodology

A literature review was carried out for each taxonomic unit that was notified to EFSA either for the QPS Opinions in 2007, 2008a, 2009 and 2010. QPS recommended taxonomic units (Table 1) and those which represent an important part of the notifications are annually reviewed. The time period of the review covered is the beginning of June 2009 until 15 April 2011 for the QPS 2011 update. Databases searched are specified in the specific sections. Keywords used are equally specified in the specific section however some common keywords such as the taxonomic unit in combination with 'toxin', 'disease', 'infection', 'clinical', 'virulence', 'antimicrobial/antibiotic/antimycotic resistance', 'safety', 'risk', 'abortion', 'urinary', 'mastitis', 'syndrome', 'vaginitis' and the animal categories 'poultry', 'chicken', 'hen', 'broiler', 'turkey', 'fowl', 'piglet', 'pig', 'calf', 'calves', 'cattle', 'cow', 'fish' and 'salmon' were generally applied. Relevant studies were evaluated, reported and discussed.

2.1.1. Taxonomy

2.1.1.1. Bacterial taxonomy

Taxonomy and nomenclature of bacteria is covered by the International Code of Nomenclature of Bacteria (Anonymous, 1992). New taxonomic units or alteration to the taxonomy and nomenclature are published in the International Journal of Systematic and Evolutionary Microbiology (IJSEM). In this journal a list appears, where all validly published taxonomic units are listed in the Notification List, i.e. the Approved List of Bacterial Names. Validly published are all taxonomic units, which are published in the IJSEM. Taxonomic units that were published outside the IJSEM are called effectively published. They appear after notification by the authors in a Validation List. Also changes in nomenclature are listed separately. These can be spelling errors in the original description or decisions of the Judicial Commission. A comprehensive and uptodate presentation of the current taxonomy and nomenclature of bacteria is given on the following website: LPSN (List of Prokaryotic names with Standing in Nomenclature Formerly List of Bacterial names with Standing in Nomenclature (LBSN) (Anonymous, 2011).

2.1.1.2. Yeast taxonomy

Rules for taxonomy of the yeasts fall under the authority of the International Code of Botanical Nomenclature which represents the official reference to validate yeast species. The most recent version of the Code (McNeill et al., 2006) was adopted at the Seventeenth International Botanical Congress, Vienna, Austria, 2005. The following is a brief discussion of the Botanical Code as it applies to yeasts. Recently, the fifth edition of 'The Yeasts, a Taxonomic Study' (Kurtzman et al., 2011) represents the latest revision of the yeast taxonomy and has incorporated the consensus view of the International Code of Botanical Nomenclature. Currently, there are 149 genera and nearly 1500 species. The application of gene sequence analysis is largely responsible for the increase in the number of taxa.

2.1.1.3. Fungi taxonomy

As of now the nomenclature and taxonomy of fungi is covered by the International Code of Botanical Nomenclature (ICBN) updated in 2005 (McNeill et al., 2006). New taxa or new taxonomic opinions are published in the international scientific literature following the rules of ICBN. Due to an intensive promotion by leading mycologists and International Mycological Association (IMA) it is now common practice to submit new taxonomic units and changes to MycoBank (http://www.mycobank.org) to avoid duplication of names and, in part, a quality check of the formalities. MycoBank is also a useful source for validity of published names, however information on synonyms is not complete as it is a matter of subjectivity. For a few genera lists of currently accepted names in use are available, but these have no official status. Article 59 in ICBN permits dual nomenclature of pleiomorphic fungi, which has caused some frustrations, as there is no logical link between two nomenclatural entities, except the organism, the fungus. The development in molecular data has proposed a new view on many anamorph-teleomorph connections and has also initiated an action to eliminate the dual nomenclature in mycology, however not all mycologists support this. The action towards one fungus should only has one name is presented by Hawksworth et al. (2011) and will be debated at the Botanical Congress August 2011.

2.1.1.4. Virus taxonomy

The taxonomy and nomenclature of viruses is the responsability of the International Committee on Taxonomy of Viruses (ICTV, www.ictv.online; Anonymous, 2010). Every three years an update is made based on proposals of working groups after adoption by the Executive Committee. The most recent update is from November 2011 (King et al., 2011). Virus taxonomy is based on shared characteristics such as (i) the type of nucleic acid (RNA or DNA), (ii) the structure of the nucleic acid (single-stranded or double stranded RNA or DNA), (iii) the polarity of the nucleic acid (positive stranded = translatable into proteins; negative stranded = nontranslatable into proteins) and (iv) the form of the virus (isometric, rod-shaped, filamentous or pleiomorph). In addition to these characters, the replication strategy of the viruses is also taking into account and contributes to their taxonomic position (Baltimore, 1971; Baltimore, 1974). Viruses are organized in orders (-*virales*), families (-*viridae*), genera (-*virus*) and species (-*virus*) by virtue of shared characteristics as described above. In contrast to organisms viruses do not have a common ancestor; therefore phylogenetic information is only partially useful in directing the taxonomy of viruses.

Plant virus taxonomy

Plant viruses cause disease in plants and many of these viruses are transmitted by vectors (insects, nematodes, fungi). The large majority of plant viruses contain positive stranded (= directly translatable) RNA as genetic information. About 1,000 plant virus species have been recognized and accommodated into two orders and 20 families (Mayo, 1999; www.ictvonline.org; Anonymous, 2010).

Baculovirus taxonomy

Baculoviruses are large DNA viruses occurring in members of the insect orders Lepidoptera (moths and butterflies), Hymenoptera (sawflies) and Diptera (flies). The family *Baculoviridae* is subdivided into four genera, *Alphabaculovirus*, *Betabaculovirus*, *Gammabaculovirus* and *Deltabaculovirus* (Jehle et al., 2006). Fourty-two baculoviruses have been recognized as a species (as of July 2011, www.ictvonline.org; Anonymous, 2010), but about 700 different baculoviruses have been described. Baculoviruses have a common ancestor assisting in the assignment of their taxonomic status.

2.1.2. Qualification regarding antimicrobial resistance in bacteria

The assessment of antimicrobial resistance in the frame of a specific notification is within the responsibility of the EFSA Scientific Panel or Unit which to which the notification was assigned. The QPS WG aims to provide general background information for their consideration and support. In particular, the generic qualification for all bacterial taxonomic units on the QPS recommended list that the strains should not harbour any acquired antimicrobial resistance genes to clinically relevant antibiotics (Table 1) is reviewed. A recent EFSA review concluded that for EFSA as a whole, the use of interpretative criteria and methods to define and monitor antimicrobial resistance have been harmonised and are reflected in EFSA's guidance documents. The use of harmonised methods and epidemiological cut-off values ensures the comparability of data over time at country level, and also facilitates the comparison of the occurrence of resistance between MSs (EFSA, 2011u).
Absence of acquired genes coding for antimicrobial resistance for QPS recommended bacterial taxonomic units is a generic qualification. Generally, it has been considered for the QPS approach that strains carrying acquired resistances should not be intentionally introduced into the food and feed chain. The scope and search for the review of antimicrobial resistance is to conduct a review of each taxonomic unit recommended for the QPS list as it was done last year. It was noticed during the last QPS update (EFSA, 2010) that the quality of the studies regarding antimicrobial resistance vary a lot. Following discussions, it seemed best to consider everything that is available and subsequently discuss potential week points in the available studies.

Suggested general search terms: susceptibility, resistance, antimicrobial, antibiotic. Additional search terms are related to acquired resistance genes in line with the generic qualification on 'not harbouring any acquired antimicrobial resistance genes'. These are: *tet, bla, vanA, vanB, vanD, vanE, vanG, vanL vanM, aac, aph, aad, arm, rmt, erm, lnu, vat, vga, ere, mef, mre, msr, mph, lin, lsa, cfr, sul, dhfr, cat, flo, qep, qnR, oqxAB* .

A point of reference for the update is the FEEDAP guidance document 'update of the criteria used in the assessment of bacterial resistance to antibiotics of human or veterinary importance' (EFSA, 2008b). This guidance document was a starting point and was used to subsequently fill any gaps during this review where possible. The list of antibiotics and the breakpoints are still valid. Focus shall be targeted towards: the presence of an acquired gene in relevant species, genera and if some new resistance mechanisms became known. New available information should be taken into consideration in this context.

3. Gram-positive non-sporulating bacteria

3.1.1. Antimicrobial resistance aspects of QPS lactic acid bacteria in general

Antimicrobial resistance is also an issue in lactobacilli and other lactic acid bacteria (LAB) and should be assessed according to international standards and guidelines (e.g. ISO/DIS 10932/IDF223, 2010) and Clinical and Laboratory Standards Institute (CLSI) guidelines (Anonymous, 2007)). For the purpose of QPS the FEEDAP guidance document (EFSA, 2008b) is of relevance.

There are several reviews and studies describing the antibiotic resistance of *Lactobacillus* species as well as other LABs (Hummel et al., 2007; Kastner et al., 2006; Klare et al., 2007; Klein, 2011b; Liu et al., 2009; Zonenschain et al., 2009). Intrinsic resistance could be shown mainly for aminoglycosides, quinolones, and glycopeptides (Hummel et al., 2007; Klein, 2011b). Moreover, the transfer of antibiotic resistance within LAB isolates from food has been recently studied (Nawaz et al., 2011; Toomey et al., 2010). Presence of genes coding for antibiotic resistances, such as *tet* (including *tet(*M*), tet(*O*), tet(*S*), tet*(W), *tet*(K), and *tet*(L)); *erm* (including *erm(*A*), erm(*B*),*and *erm*(C)) (Hummel et al., 2007; Ammor et al., 2008) have been reported. This is a non-comprehensive list.

3.1.2. *Bifidobacterium* species

No case reports could be retrieved by literature search within Pubmed and the respective search terms. Only one report pointing on the relevance of *Bifidobacterium* spp. and also Scardovia and Parascardovia for severe early childhood caries (Kanasi et al., 2010) could be found on the clinical relevance of bifidobacteria. This is a confirmation of earlier reports for caries in general, but no specific taxonomic units within the bifidobacteria were identified. The relevance of bifidobacteria in the development of dental caries is comparable to lactobacilli and the same conditions apply as reported under section 3.1.5. Therefore, the QPS recommendation is confirmed.

3.1.2.1. Antimicrobial resistance aspects regarding the qualification

A recent paper about ‘medium level’ tetracycline resistance in *Bifidobacterium animalis* subsp. *lactis* showed the presence of *tet*(W) gene (Gueimonde et al., 2010). The *tet*(W) gene was associated with the tetracycline resistance in this subspecies. Several tet genes have been already described to be present in bifidobacteria, including *tet*(W) gene (Gueimonde et al., 2010). The relevance for *Bifidobacterium animalis* subsp. *lactis* lies in the wide distribution of this species within food. There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.3. Corynebacteria

A literature review did not reveal new information about adverse health effects or on safety concerns since the last update (EFSA, 2010). The QPS recommendation has been confirmed.

3.1.3.1. Antimicrobial resistance aspects regarding the qualification

While no actual antibiotic MIC determinations for *Corynebacterium glutamicum* appear to have been done, the antibiotic sensitivity of a strain used for amino acid production, has been tested using a disc method (Costa-Riu et al., 2003). The strain was sensitive to ampicillin, kanamycin, streptomycin, tetracycline, susceptible to gentamicin and resistant to norfloxacin, and chloramphenicol. However, the susceptibility test was not performed according to the methodology recommended by the CLSI guideline (Anonymous, 2007). There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.4. *Enterococcus* species

Enterococci are commensal bacteria of the gastrointestinal tract of humans and other mammals, and are frequently found as members of the bacterial communities of food fermentations. Taxonomy of this genus has evolved, and currently, more than 30 species have been described. Among these, *Enterococcus faecium* is the most encountered species in food fermentations, such as cheese, fermented vegetable and sausages. This microorganism is also intentionally introduced in the food chain as feed additive (animal probiotic), under a specific EU regulation which requires risk assessment by EFSA, or as food starter culture (Official Journal of the European Union, 2003).

Enterococcus faecium is also an important cause of infections in hospitalized or immunocompromised patients and the high prevalence of antimicrobial resistance in strains, limits the therapeutic treatments. A new literature search within Pubmed, restricted to the last 12 month, confirmed this view with an increase number of reported infections casused by drug resistant *Enterococcus faecium.*

The assessment of *Enterococcus faecium* for QPS has been performed by EFSA in 2010 (EFSA, 2010), reaching the conclusion that a strain specific evaluation is necessary to assess the risk associated to the intentional use of enterococci in the food chain.

Available scientific data support the view that safety of *Enterococcus faecium* is a strain-related property, and that specific qualifications cannot be applied, therefore confirming the previous view that *Enterococcus faecium* should not be recommended for the QPS list.

3.1.4.1. Update of antibiotic resistance aspects

Enterococci show intrinsic resistance to several beta-lactams, low-levels of aminoglycosides, and trimethoprim-sulfamethoxazole. Additional intrinsic resistances to lincosamides and vancomycin are characteristics of specific enterococcal species (Leclerq and Courvalin, 2005; Murray, 1990). Mobile genetic determinants conferring resistance to different classes of antibiotics such as aminoglycosides [*aph(3')-III*, and *aac(6')* and *aph(2'')* variants], ß-lactams (*bla, pbp5*), glycopeptides (*vanA/B/D/E/G/L/M*), phenicols (*cat* genes) tetracyclines (*tetO/L/K/S/U*), and to macrolides, lincosamides and streptogramins group (*ermA/B/C/F/T, lnuB, vatB/D/E, msrA/C/D, lsaA, vgaB* and *mefA*) have been observed in enterococci from different sources, including in food producing animals and food strains (Cocconcelli et al., 2004; Freitas et al., 2011; Hegstad et al., 2010; Hummel et al., 2007; Rizzotti et al., 2005; Vignaroli et al., 2011).

3.1.5. *Lactobacillus* species

Since the 2010 update only few reports have been published concerning lactobacilli and clinical infections according to a PubMed search including 'clinical infection' and ´disease´. Additional search terms for lactobacilli are proposed: 'bacteremia', 'urinary tract infection', 'vaginal infection', 'gingivitis'.

One article from Turkey (Doğan and Baysal, 2010) detected a '*Lactobacillus acidophilus* or *Lactobacillus jensenii*' strain in clinical specimen amongst other species in an immunocompromised patient. The clinical relevance of this isolate was not clear. In addition, the taxonomic identification was done with the API system and therefore no clear attribution to a taxonomic unit can be done. Several reports related to the well known association of lactobacilli with dental caries (Kneist et al., 2010; Mathias and Simionato, 2011; Nagarajappa and Prasad, 2010). Kneist et al. (2010) found five species from carious dentine: *Lactobacillus paracasei* subsp. *paracasei*, *Lactobacillus paracasei* subsp. *tolerans*, *Lactobacillus rhamnosus*, *Lactobacillus gasseri*, and *Lactobacillus alimentarius*. They concluded that *Lactobacillus rhamnosus* and *Lactobacillus paracasei* subsp. *paracasei* occurred in all caries progression stages, whilst the other species were found only sporadically. There is a connection to endocarditis via caries which has been reported on several occasions earlier. There is also a possibility of lactic acid bacteria (LAB) being involved in endocarditis after dental surgery (Noti et al., 2009). Caries is a multifactorial disease, including bacteria from the oral cavity, eating and drinking habits (high sugar amounts) and insufficient oral and dental hygiene (Takahashi and Nyvad, 2011). Bacteria involved change through different stages of caries proliferation. In the primary phase mainly mutans streptococci are involved, whereas in secondary caries with lesions already present also lactobacilli, bifidobacteria and other LAB are involved (Ito et al., 2011; Takahashi and Nyvad, 2011). The conclusions of these studies are that without bacteria caries development is not possible. LAB, however, are present in caries stages with predisposing factors such as lesions and insufficient dental hygiene. The origin of those LAB (if deriving from food or as autochthonous oral microflora) has not been studied so far. In conclusion, LAB are not the initial cause of these diseases and they are present in the human organism as commensal microflora. This has no relevance for the QPS recommendation.

Doi et al. (2010) found *Lactobacillus paracasei* involved in a splenic abscess. But again as in previous similar case reports, the patient had an underlying disease and was immunocompromised. In a similar case with an immunocompromised patient (stem cell transplantation in a child) *L. rhamnosus* was found to be the causative agent for meningitis after recurrent episodes of bacteremia (Robin et al., 2010). Russo et al. (2010) isolated a presumptive *Lactobacillus casei* strain from a bacteraemia case, where heavy consumption of dairy products was involved in the case history. However, no strains from dairy products (mainly cheese) were isolated and compared to the clinical strain. The identification was most probably misinterpreted, as only a 16S rDNA sequence analysis was done, which matched equally to *Lactobacillus casei* and *Lactobacillus paracasei*. Therefore *Lactobacillus paracasei* seems to be the correct identification given the distribution of species in humans and dairy products. *Lactobacillus casei* does not naturally occur in such environments. *Lactobacillus rhamnosus* can be associated with unexplained sustained bacteremia like in the TIPSS syndrome (tipsitis). This is a rare disease where *Lactobacillus rhamnosus* may be involved inter alia (Kochar et al., 2010).

A research including ´urinary tract infection´ (UTI) revealed one review (Bernier et al., 2010) indicating a relatively higher risk for elderly women for urinary tract infections with *L. delbrueckii*. However, in general UTIs were reported seldom. The search term ´vaginal infection´ did not reveal more cases.

In conclusion, there is no need to change the QPS recommendation of the previously recommended *Lactobacillus* species.

3.1.5.1. Antimicrobial resistance aspects of lactic acid bacteria with regards to the qualification

Intrinsic resistance could be shown mainly for aminoglycosides, quinolones, and glycopeptides (Hummel et al., 2007; Klein, 2011b). Acquired resistance genes are also known, especially the following: *tet* (including *tet(*M*), tet(*O*), tet(*S*), tet*(W), *tet*(K), and *tet*(L)); *erm* (including *erm(*A*), erm(*B*)* and *erm*(C)) (Hummel et al., 2007; Ammor et al., 2008). This is a non-comprehensive list. There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.6. *Lactococcus* species

New human case reports related to infections caused by *Lactococcus lactis* have been published recently, including a liver abscess and empyema in an imunocompetent adult (Kim et al., 2010) and a bacteremia in an infant suffering from necrotizing enterocolitis and receiving total parentheral nutrition via silicone catether (Glickman et al., 2010) and an endocarditis in a middle aged man complicated by intracerebral haemorrhage and leading to the death of the patient (Lin et al., 2010). In all these cases the causative microorganism was typed as *Lactococcus lactis* ssp. *cremoris.* In none of these cases a connection between consumption of raw milk or other dairy products (not even mother's milk in the infant case) was identified.

In a report from 2006 (Goyache et al., 2006) an infection by *Lactococcus lactis* ssp. *lactis* in lungs, liver and spleen of five birds (one mallard, three shovelers, and one coot) obtained from a mass die-off of waterfowl in southwestern Spain has been described.

While these recent findings do not warrant any reconsideration of the QPS status of *Lactococcus lactis*, some further study on both human and veterinary clinical isolates should be considered to find out any possible strain specific factors that might contribute to the pathogenicity.

3.1.6.1. Antimicrobial resistance aspects with regards to the qualification

According to the survey reported by Flórez et al. (2008) the lactococcal strains are generally susceptible to ampicillin, chloramphenicol, gentamicine and vancomycin, while intrinsically resistant to streptomycin. Occasional tetracycline resistances occur, associated, among others, with *tet*(S) and *tet*(M) genes. The findings do not contradict the MIC cut-off values proposed in the latest EFSA update of the antimicrobial resistance criteria (EFSA, 2008b). There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.7. *Leuconostoc* species

Three species of the genus *Leuconostoc*, *Leuconostoc citreum, Leuconostoc mesenteroides* and *Leuconostoc lactis*, were previously given a QPS recommendation. A fourth species, *L. pseudomesenteroides*, was considered unsuitable because of a limited body of knowledge on food and feed application and of its (rare) implication in opportunistic infections. Since 2010, a new report of three *Leuconstoc* infections in patients with malignancy, receiving intensive chemotherapy was published (Ishiyama et al., 2011). In none of the three cases the species was identified.
In conclusion, the QPS recommendations of the three *Leuconostoc* species are confirmed.

3.1.7.1. Antimicrobial resistance aspects with regards to the qualification

No new relevant information in the last year was published and the genus is covered by general section on lactic acid bacteria 3.1.1. There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.8. *Pediococcus* species

Bernabeu et al. (2011) report an association between *Pediococcus* species and liver abscess. The patient had a long history of Crohn´s disease and this is a very rare complication, according to the literature search of the authors. Therefore this is another example of rare infections by *Pediococcus* species in case of underlying severe diseases and immunocompromised patients. The QPS recommendations for the *Pediococcus* species are confirmed.

3.1.8.1. Antimicrobial resistance aspects with regards to the qualification

No new relevant information in the last year was published and the genus is covered by general section on lactic acid bacteria 3.1.1. There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.9. *Oenococcus oeni*

No case reports for clinical infections were found for *Oenococcus oeni*. The state of the previous EFSA opinion is still valid (EFSA, 2010). Therefore the QPS recommendation for *Oenococcus oeni* is maintained.

3.1.9.1. Antimicrobial resistance aspects with regards to the qualification

No new relevant information in the last year was published and the genus is covered by general section on lactic acid bacteria 3.1.1. There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.10. Dairy propionic acid bacteria

A review revealed no new relevant information regarding human and animal infection which would require a reconsideration of the QPS recommendation of *Propionibacterium freudenreichii* and *Propionibacterium acidopropionici*. Therefore, they remain on the list of microorganisms recommended for QPS.

3.1.10.1. Antimicrobial resistance in propionic acid bacteria with regards to the qualification

The data on the antibiotic resistance patterns following a search in the PubMed database using keywords "*Propionibacterium*" and "Antibiotic resistance" does not indicate new relevant studies on dairy strains. One publication on the probiotic aspects of propionic acid bacteria (Suomalainen et al., 2008), however, reports MICs of ampicillin, erythromycin, virginiamycin, gentamicin, streptomycin, kanamycin, tetracycline, chloramphenicol, vancomycin, narasin, bacitracin and linezolid for four specific *Propionibacterium freudenreichii* strains determined with the microdilution method. The values obtained are in good agreement with the proposed EFSA breakpoints, although a larger panel of strains should be screened in order to get a final confirmation of the EFSA breakpoints (EFSA, 2008).
There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.11. *Streptococcus thermophilus*

No reports of clinical infections related to *Streptococcus thermophilus* were identified in scientific literature since 2009. Therefore, the QPS recommendation for this species is maintained.

3.1.11.1. Antimicrobial resistance of *Streptococcus thermophilus* with regards to the qualification

Although few scientific information is still available on the *Streptococcus thermophilus* susceptibility to clinically relevant antibiotics, recent papers have shown the occasional presence of acquired resistance genes in this dairy bacterium. *Streptococcus thermophilus* strains which are phenotypically resistant to erythromycin, tetracycline and streptomycin have been reported by Tosi et al. (2007).
The presence of acquired resistance genes, the erythromycin resistance determinant *ermB* and the tetracycline-resistance genes *tet*(S), *tet*(M), and *tet*(L) were detected in dairy strains of *Streptococcus thermophilus* (Rizzotti et al., 2009). These resistances are covered by the general qualification on antibiotic susceptibility. There is no new information that would require a modification in the qualification of the antimicrobial resistance.

4. Gram-positive spore forming bacteria

4.1.1. *Bacillus* species

Concerning *Bacillus* species include in the QPS list, the following notifications were received since the last QPS Opinion (Appendix A):

Bacillus amyloliquefaciens (Feed additive, enzyme production)

Bacillus amyloliquefaciens subsp *plantarum* (Pesticides)

Bacillus lentus (enzyme production)

Bacillus megaterium (production of vitamin C)

Bacillus pumilus (plant protection products)

Bacillus subtilis (production vitamin B_2 and enzyme production)

4.1.1.1. Update of the body of knowledge on safety concerns for *Bacillus* species on the QPS list

A search on the Web of Science from 2010 to end of April 2011 with any of the key words "toxin, enterotoxin, lipopeptide, peptide, disease, infection, virulence, abortion, mastitis, bacteremia, poisoning, hepatitis, necrosis, necrotizing, pneumonia, endophthalmitis, gangrene, endocarditis, urinary tract, meningitis, encephalopathy, parodontitis", combined with "*Bacillus*" (excluding cereus, anthracis and thuringiensis) retrieved 162 articles. This first search was completed by a second one with any of the key words "poultry, chicken, hen, broiler, turkey, fowl, piglet, pig, calf, calves, cattle, cow, fish, salmon" combined with "*Bacillus*" (excluding cereus, anthracis and thuringiensis) which found 64 articles. After examination of some of these articles, a third search combining "*Bacillus*" with "liver or hepatotoxic" identified 168 more articles.

All these articles were screened. Most were not relevant. Few (Coutte et al., 2010; Liu et al., 2011; Tabbene et al., 2011; Raaijmakers et al., 2010; Thasana et al., 2010) concerned the antifungal or antimicrobial activities of *Bacillus* species and indicated that at least part of the activity was due to the peptidolipides (e.g., surfactin, fengicin, iturin) which are also suspected of being involved in the rare foodpoisoning cases caused by *Bacillus* species other than *Bacillus cereus* (EFSA, 2008a). Such *Bacillus* strains producing these lipopeptides would not meet the qualification "Absence of toxigenic activity" specified for *Bacillus* species in the QPS approach.

One article (Lopez and Alippi, 2010) reports the characterisation of a *Bacillus megaterium* (a QPS *Bacillus* species) strain with the genes of the cytotoxin K and of the full enterotoxin HBL operon, two toxins involved in the virulence of the foodborne pathogen (and non QPS species) *Bacillus cereus*. The hemolysis pattern of this strain suggested the production of active HBL enterotoxin. The identification of the *Bacillus megaterium* strains, presented in Lopez and Alippi (2009), indicates that this was presumably not misidentified *Bacillus cereus*. The *cytK* and *hbl* genes were detected in the *Bacillus megaterium* strain by PCR. The sequence of the amplified PCR fragment would have been needed for a full confirmation. In any case, this strain of *Bacillus megaterium* would not meet the qualification "Absence of toxigenic activity" specified for *Bacillus* species in the QPS approach. Therefore, there is no need to change the QPS recommendation for *Bacillus megaterium*.

An infective arthritis with *Bacillus* species was reported (Wiedermann et al., 2010). However the infection was the results of an arthroscopy and had presumably no link with the food chain. No change to the position of *Bacillus* species in the QPS list is needed.

An acute hepatitis of a young adult was linked to the consumption of a dietary supplement (Krones et al., 2010) and the authors suspected toxigenic *Bacillus* isolated from the dietary supplement to have caused the disease. The two toxigenic strains were identified as one *Bacillus cereus* and one from the *Bacillus subtilis* group. The method used in this work to identify the strains (16S rDNA sequencing) is not able to distinguish all the strains within the *Bacillus subtilis* group. However, the species from the *Bacillus subtilis* group are on the QPS list, so it is possible that this hepatitis was at least partly caused by a *Bacillus* included in the QPS list. This paper refers to a previous report of several similar severe hepatotoxicity associated to the consumption of another dietary supplement contaminated with toxigenic *Bacillus subtilis* (Stickel et al., 2009). In the latter work, *Bacillus cereus* was not isolated from the dietary supplement and the *B. subtilis* strains were adequately identified using both 16S rDNA and *gyrB* sequences. In both works, the cytotoxins were detected in the supernatant of the strains grown in the laboratory, but not in the dietary supplements, indicating a likely infection of the patient by the *Bacillus* and production of the toxins in the patient, instead of an intoxination (i.e. production of the toxin in the food). However the works did not quantified the numbers of *Bacillus* present in the dietary supplements and Stickel et al. (2009) and Seff (2009) discuss a possible contribution of the supplement itself to the hepatotoxicity. In any case these two articles are the first reports of such severe disease possibly caused by ingestion of *Bacillus subtilis* related species or its toxins. These strains would be excluded from the QPS recommendation because of toxin formation and would not meet the qualification “Absence of toxigenic activity” specified for *Bacillus* spp in the QPS approach. Therefore, there is no need to change the QPS recommendation for *Bacillus subtilis*.

4.1.1.2. Antimicrobial resistance among QPS *Bacillus* species with regards to the qualification

Few reports on antimicrobial resistance to relevant antibiotics among *Bacillus* species were published in the last year. Particularly of concern was the description in a swine *Bacillus* spp. of a plasmid encoding *ermB* and *cfr* gene (Dai et al., 2010). The *cfr* gene, previously described only in staphylococci, encode an RNA methyltransferase that affects an array of ribosomal antibiotics, including phenicols, oxazolidinone, lincosamides, pleuromutillins and streptogramin A (Long et al., 2006; Dai et al., 2010). Moreover, a chromosomally located *fexA* gene, encoding resistance to phenicols and associated with a defective Tn558 transposition was also identified. Remarkably, plasmidic and transposon structures associated with these genes are similar to the ones observed in staphylococci, streptococci and enterococci being worrisome the possibility of its dissemination to pathogenic human and animal isolates (Dai et al., 2010).

Tetracycline resistance genes *tet*(M) and *tet*(K) were previously described in some isolates of different environmental *Bacillus* species conferring resistance to tetracycline (Neela et al., 2009; Nikolakopoulou et al., 2008). Recently, a tetracyclin resistance gene *tet*(L) transferable to a *Bacillus subtilis* was observed in a *Bacillus* spp. strain isolated from a marine sponge *Haliclona simulans* (Phelan et al., 2011).

In conclusion, the available data reinforces the possibility of emergence of important resistance genes in members of the *Bacillus* genus, confirming the importance of the qualification regarding antimicrobial resistance in the QPS approach.

There is no new information that would require a modification in the qualification of the antimicrobial resistance.

4.1.2. *Clostridium* species

Clostridium butyricum was assessed this year for the first time.

4.1.2.1. Taxonomy

The genus *Clostridium* is composed by 202 different species that do not form a phylogenetically coherent group. Thus, Gram-positive, anaerobic rods forming endospore were originally assigned to this genus. A phylogenomic and comparative analyses made using data derived from sequenced clostridial genomes allowed to analyse the evolutionary relationships among species of *Clostridia* (Gupta and Gao, 2009). *Clostridium butyricum* is the type species of the genus.

4.1.2.2. Toxigenic potential of *Clostridium butyricum*

Strains of *Clostridium butyricum* are able to form botulinum neurotoxin type E, harbouring *BoNT/E* gene on a large plasmid (Hauser et al., 1992; Peck 2009). Toxigenic strains of this species were responsible for infantile botulism (Fenicia et al., 1999; Abe et al., 2008) and involved in foodborn intoxications. The gene coding for botulinum neurotoxin type E was detected only in a minority of *Clostridium butyricum* strains (Hauser et al., 1992). The body of knowledge on human and animal exposure to *Clostridium butyricum* is limited.

This information supports the view that safety of *Clostridium butyricum* is a strain-related property, therefore *Clostridium butyricum* should not be recommended for the QPS list.

4.1.2.3. Antimicrobial resistance aspects

A recent study reports the antibiotic susceptibility and genetic resistance determinants of *Clostridium butyricum* strains isolated from the faeces of infants (Ferraris et al., 2010). All the strains were susceptible to cefoxitin, imipenem, vancomycin, tigecycline, metronidazole, chloramphenicol and linezolid. Resistance was observed to clindamycin (100%), penicillin G, amoxicillin and piperacillin (15%), tetracycline (7.5%) and erythromycin (5%). The genetic basis of these resistances demonstrated that penicillin resistance was related to *β*-lactamase activity and that tetracycline resistance was due to *tet(O)* or *tet(O/32/O)* homologue genes.

5. Gram-negative bacteria

5.1.1. *Ensifer* species

This species was assessed this year for the first time.

5.1.1.1. Taxonomy

The genus *Ensifer* is a valid taxonomic unit as are also the species *Ensifer adhaerens* and *Ensifer fredii*. However, the genus *Sinorhizobium* (Chen et al., 1988) and its *Sinorhizobium morelense* (Wang et al., 2002) are a later synonym of *Ensifer adhaerens* (Anonymous, 2008; Casida, 1982; Young, 2003). Also the combination '*Sinorhizobium adhaerens*' has been cited in the literature (Casida, 1982; Willems et al., 2003). Therefore, case reports including these no longer valid synonyms should also be considered. *Ensifer fredii* has also been described as *Sinorhizobium fredii* or was refered to as belonging to the genus *Rhizobium* as *Rhizobium fredii*. Therefore, also in case of *Ensifer fredii* those invalid taxonomic combinations should be considered for literature research.

5.1.1.2. Safety assessment

Ensifer adhaerens was first characterized as a predator of bacteria (Casida, 1982; Germida et al., 1983). Species of the genus *Ensifer* are also legume symbionts forming root nodules and fixing nitrogen (Merabet et al., 2010; Rogel et al., 2001; Sawada et al., 2003).

'Ensifer' was searched as key words in the topic of articles on the Web of Sciences, from 1975 to 2011. 110 articles were found, all were screened. *Ensifer adhaerens* was first characterized as a predator of bacteria (Casida, 1982; Germida et al., 1983). No article mentioned human or animal safety concerns.

'*Sinorhizobium*' (Title) was combined with toxin or enterotoxin or lipopeptid or peptid, disease or infection or virulence or abortion or mastitis or bacteremia or poisoning or hepatitis or necrosis or necrotizing or pneumonia or endophthalmitis or gangrene or endocarditis or urinary tract or meningitis or encephalopathy or parodontitis (topic) in the Web of Sciences from 1975 to 2011.

108 articles were found. All were screened. No article mentioned a safety concern for human or animals. The reference to 'infection' referred to infection of plant tissues in the course of plant pathogens interactions for nodules formation.

Ensifer fredii was also referred to as *Rhizobium fredii*. '*Rhizobium fredii*' was used as search term for titles in the Web of Sciences, from 1975 to July 3rd 2011. 100 articles were retrieved. All were screened and dealt with symbiosis with plants. None reported safety concerns for human or animals.

'Rhizobium fredii' (title) was combined with toxin or enterotoxin or lipopeptid or peptid, disease or infection or virulence or abortion or mastitis or bacteremia or poisoning or hepatitis or necrosis or

necrotizing or pneumonia or endophthalmitis or gangrene or endocarditis or "urinary tract" or meningitis or encephalopathy or parodontitis" (topic) in the Web of Sciences from 1975 to July 3rd 2011. 62 articles were retrieved. All were screened and dealt with plant tissue infection for nodulating activity. None concern infection of human or animals.

In conclusion, the body of knowledge of these two species concerns the ecology in the soil and the interaction with the plant root and does not give information on safety in the food and feed chain. Therefore, both species cannot be recommended for the QPS list.

5.1.1.3. Antimicrobial resistance aspects

In all papers screened, none of them mentioned antimicrobial resistance aspects.

5.1.2. *Ketogulonicigenium* species

This species was assessed this year for the first time.

5.1.2.1. Taxonomic aspects

So far *´Ketogulonicigenium vulgare´* has not been validly published published and therefore has from a taxonomic point of view no standing in nomenclature, despite of the notification in the notification list of the IJSEM (Anonymous, 2001; Urbance et al., 2001). Therefore *´Ketogulonicigenium vulgare´* is so far no officially acknowledged taxonomic unit. The reason is that at the time of publication, the type strain was not deposited in two publicly accessible service collections in different countries. The authors could submit evidence of the deposit of the type strain in additional collections to the List Editor of IJSEM before the next meeting of the Judicial Commission in Sapporo, Japan, in 2011, and the species can be considered as validly published afterwards. There are also spelling corrections, which should be considered for literature research: *´Ketogulonicigenium vulgare´* is sometimes referred to as *´Ketogulonicigenium vulgarum´*, and the genus name has been corrected upon notificiation from *´Ketogulonigenium´* to *´Ketogulonicigenium´*. These spelling differences should be therefore considered.

5.1.2.2. Safety aspects

Ketogulonicigenium vulgare can produce ascorbic acid from various substrates (Sugisawa et al. 2005).

The web of sciences was search for *Ketogulonigenium* or *Ketogulonicigenium* as topic, from 1975 to July 3rd 2011. 15 articles were found. All were screened and concerned vitamin C production. None reported safety concerns for human or animals, including antimicrobial resistance aspects.

In conclusion, due to the little body of knowledge apart from this very specific usage, it cannot be recommended for the QPS list.

5.1.2.3. Antimicrobial resistance aspects

In all papers screened, none of them mentioned antimicrobial resistance aspects.

6. Yeast

The yeast species recommended for the QPS list are *Debaryomyces hansenii*, *Hanseniaspora uvarum*, *Kluyveromyces lactis* and *Kluyveromyces marxianus, Saccharomyces bayanus*, *Saccharomyces* *cerevisiae*, *Saccharomyces pastorianus*, *Schizosaccharomyces pombe* and *Xanthophyllomyces dendrorhous* (imperfect form *Phaffia rhodozyma*), and for enzyme production purposes, *Komagataella pastoris*, *Lindnera jadinii* (formerly *Pichia jadinii*), *Pichia angusta* and *Wickerhamomyces anomalus*. During the review period, only few studies concerning safety aspects of these yeasts, including infections, disease, clinical significance, virulence and toxins were published.

Saccharomyces cerevisiae which is recommended for the QPS list based on a long history of safe use has also been implicated in human infections (EFSA, 2007; EFSA, 2008a). A literature review for the preceeding year has not revealed any information that affected the recommendation for the QPS list (EFSA, 2009; 2010). During the last year, some manuscripts have been published concerning *Saccharomyces cerevisiae*. Some of them were included in the previous QPS report (EFSA, 2010). Recently, de Llanos et al. (2011) used two murine models (BALB/c and DBA/2N mice) to test clinical and commercial *Saccharomyces cerevisiae* strains by intravenous application. Considering the challenge conditions of this model it has limited significance for the recommendation of this species for the QPS list. There is a long history of safe use for *Saccharomyces cerevisiae* and the QPS recommendation is therefore maintained.

The QPS recommendations of the last year can be confirmed for all other yeast species because no significant publications appeared during the last year related with clinical studies (EFSA, 2010).

6.1.1. *Xanthophyllomyces dendrorhous* (imperfect form: *Phaffia rhodozyma*)

Xanthophyllomyces dendrorhous is the only species of the genus *Xanthophyllomyces* and the anamorph or imperfect form is *Phaffia rhodozyma*. The present view that *Xanthophyllomyces* is limited to one species is due to lack of information on the genetic variability within the genus and the difficulty to examine cross strain mating studies, due to the primary cell/bud mode of sexual reproduction. The genetic variability has been explored in three regions of the rRNA gene (ITS, D1/D2 LSU and IGS1). D1/D2 analysis of 27 strains (Fell et al., 2007) demonstrated that all of the *Xanthophyllomyces* strains have identical sequences. However small variability has been observed in strain of *Phaffia rhodozyma,* due to this situation, both names are accepted in the the fifth edition of The Yeasts, a Taxonomic Study (Kurtzman et al., 2011). This species produces the high-value carotenoid astaxanthin. This pigment or appropriate precursors must be included in the animals' diets to obtain their characteristic pigmentation.

Since both forms have the same application and record of safe use, both forms are recommended for the QPS list.

6.1.2. *Trichosporon*

The *Trichosporon mycotoxinivorans* species belongs to the *Trichosporon* genus of basidiomycetous anamorphic yeasts. This species was first isolated in 1996 from the hindgut of the lower termite *Mastotermes darwiniensis* (Prillinger et al., 1996). The name of this species refers to its ability to detoxify mycotoxins such as ochratoxin and zearalenone. Some strains of this species were shown to detoxify ochratoxin A by cleavage of the phenylalanine moiety from the isocumarin derivate to ochratoxin α, a metabolite that has been described to be non-toxic or at least 500 times less toxic than ochratoxin A (Schatmayr et al., 2006). *Trichosporon mycotoxinivorans* is also able to metabolize Zearalenone in a metabolite (ZOM-1) that apparently shows no estrogenic activity anymore (Vekiru et al., 2010). Some recent results also support the potential of cell walls from *Trichosporon mycotoxinivorans* to bind enteropathogenic bacteria (*E. coli* spp and *Salmonella* spp) while having no adverse effect against beneficial or commensal bacteria (Ganner et al., 2010). However, a study by Hickey et al. (2009) described *Trichosporon mycotoxinivorans* as a novel respiratory human pathogen having a propensity for patients with cystic fibrosis and reported four cases of recognized *Trichosporon mycotoxinivorans* pneumonia. According to this last report and due to the limited body of knowledge on human and animal exposure, *Trichosporon mycotoxinivorans* is ineligible for QPS status.

6.1.3. Qualification for yeast regarding resistance to antimycotics

With regards to the QPS update 2010, the section of antifungal drugs was updated. During the last year two major reviews about emerging opportunistic yeast infections and resistance patterns were published (Miceli et al., 2011; White and Hoot, 2011). In the cases of QPS species only for *Saccharomyces* species and for *Wickerhamomyces anomalus* data are available. For both more than 90% of isolates tested are sensitive to polyenes (amphotericin B formulations), echinocandins (caspofungin) and voriconazole and 60–89% of isolates tested for fluconazole. In the cases of *Wickerhamomyces anomalus,* 40–59% of isolates tested were reported sensitive to itraconazole. Very few data are available for drug efficacy but amphotericin B and voriconazole seem to be active in vitro against *Saccharomyces cerevisiae* whereas, fluconazole might be variable in activity (Miceli et al., 2011). It should be noted that some therapeutic antifungal agent can have severe secondary effects which limit their usage.

Where *Saccharomyces cerevisiae* is the cause of a systemic infection it should be possible to cure the patients using available drugs. As the optimal growth temperature for this yeast is 30 °C and is not normally associated with infection the qualification is relevant to strains with an unusually high optimum growth temperature. For these strains susceptibility testing is recommended.

Antifungal susceptibility testing is recommended for *Wickerhamomyces anomalus* and *Saccharomyces cerevisiae* strains able to grow at temperatures equal to or above 37° C. This qualification is only relevant if viable yeasts are intentionally introduced into the food chain.

7. Filamentous fungi

Filamentous fungi are important agents for intentional addition and use along the food chain. Therefore, even though no recommendation for the QPS list is anticipated in the near future, an updated knowledge on developments in this field and of the body of knowledge is considered essential in support of risk assessment that are carried out by EFSA. The body of knowledge on fungi in fields relevant for assessment of strains notified to EFSA is rapidly moving (e.g. methods for identification of strains, safety concerns for humans, nature and diversity of toxic compounds produced, conditions leading to toxin productions). The yearly update done in the QPS Opinions provides regular, useful and consistent information on fungal species of importance for EFSA (see section 1.2. of this opinion).

The general body of knowledge on filamentous fungi has been updated in the present Opinion, considering in particular the progress and limitation in the taxonomy, in the knowledge of metabolic pathways and in the identification of the production of toxic compounds. New issues were considered, such as the resistance of fungi to therapeutic antifungal agents and the risks linked to the use of fungi as plant protection products. Where a species or genus is not mentioned in the specific sections in the text of the body of this opinion, a remark on the outcome of the 2011 review was included in the notification table (Appendix A).

New notifications assessed since the 2010 QPS update (EFSA, 2010) were received for *Ampelomyces quisqualis, Ashbya gossypii, Aspergillus aculeatus* and *Trichoderma asperellum.*

7.1.1. *Ampelomyces*

This species was assessed this year for the first time. *Ampelomyces quisqualis* complex is reported as the most common and widespread pycnidial hyperparasite of the family Erysiphaceae, the cause of powdery mildew diseases (Kiss et al., 2004). Isolates from the genus *Ampelomyces* were among the first mycoparasites to be studied in detail (first described in 1930) and were also the first fungi used as biocontrol agents of plant parasitic fungi. Since 1996, a commercial product called AQ-10 is available. This biofungicide is a pelleted formulation of conidia of *Ampelomyces quisqualis* isolate M-10. Since 1980 this product has been found to be tolerant with some fungicides, so it is recommended to be used in an integrated approach in combination with chemical pesticides. In studies of its mode of action (Kiss, 2003) *Ampelomyces quisqualis* is shown to colonize hyphae of powdery mildews to continue its growth internally, and it produces the pycnidia in the cells of the hyphae, conidiophores and immature cleistothecia of its fungal hosts. Thus, this intracellular mycoparasite suppresses the sporulation of the attacked powdery mildew mycelium and kills the parasitized cells. There is still an ongoing debate on the taxonomy of the genus *Ampelomyces*. Although its genetic diversity has been investigated during the last five years and four distinct groups identified according to sequences divergence in the ITS rDNA and actin genes (Park et al., 2010), a single name is still applied to all pycnidial intracellular hyperparasites of powdery mildew (inducing a high possibility of confusion with isolates of *Phoma glomerata*, according to Sullivan and White (2000)). Recently, it has been reported that the host specificity of *Ampelomyces* isolates was not so pronounced since some isolates were shown to be able to infect powdery mildew species they were unlikely to have encountered in nature (Kiss et al., 2011). This raises the risk of non-target effects with potential ecological impacts associated with the release of this biological agent (Brimner and Boland, 2003). According to the two toxicological reports included in the North America pesticide database (PAN) and the European pesticide properties database (PPDB), there is no evidence of adverse effects in animal and human exposed to *A. quisqualis* isolate M-10 and no indication of hypersensitivity was reported. There have been no reported cases of adverse reactions associated with the production of the biological fungicide.

However, despite their apparent safe use as biocontrol agents, it has not been possible through extensive literature searches to verify a general absence of biological active secondary metabolites from *Ampelomyces quisqualis* isolates. Taxonomy of this genus requires also to be elucidated. Thus, this species cannot be proposed for QPS status.

7.1.2. *Ashbya*

This species was assessed this year for the first time. *Ashbya gossypii* is a filamentous ascomycete fungus with the smallest genome known for a free-living eukaryote yet characterized. With its close ties to yeast and a facility of genetic manipulation, *Ashbya gossypii* is well suited as a model to elucidate the regulatory networks that govern the functional differences between filamentous growth and yeast growth. This explains the numerous publications (more than 150, according to a Web of Science search) that have been devoted to this species during the last ten years. The genome of *Ashbya gossypii* has been sequenced and annoted in 2004, 90 % of the genes present in the genomes of *Ashbya gossypii* and *Saccharomyces cerevisiae* were found to be orthologous and syntenic (Dietrich et al., 2004). *Ashbya gossypii* is also a riboflavin-producing filamentous fungus that converts vegetable oil to vitamin B2 in a "one-step reaction". Potential to produce riboflavin is a common trait in this fungal species with the occurrence of high and low-producing strains. Together with *Candida famata* and *Bacillus subtilis*, *Ashbya gossypii* belongs to the three most common microorganisms that are currently in use for industrial riboflavin production (Stahmann et al., 2000). The productivity and selectivity of this microorganism have been improved significantly over the years, with the identification of overproducing mutants or the use of genetically modified strains. An extensive literature search did not reveal any information on toxic metabolites from this species. However, in the future, the knowledge of *Ashbya gossypii* should allow identifying genes cluster involved in the biosynthesis of toxic secondary metabolites.

The body of knowledge concerning the capacity of *Ashbya gossypii* to produce biological active secondary metabolites remains limited and this species cannot be proposed for QPS status.

7.1.3. *Aspergillus* species

Among the quite many new papers on *Aspergillus* species there are no relevant reports on the lack of toxicity or toxin production. Most reports on *Aspergillus niger* and *Aspergillus oryzae* deal with the genetic regulation of enzyme production or the industrial production of metabolites. There are also some reports on food spoilage and mycotoxins contamination by *Aspergillus niger*.

7.1.3.1. Aspergillus aculeatus

This species was assessed this year for the first time. The notified *Aspergillus aculeatus* is a tropical species within the black aspergilli complex and has been reported to produce the mycotoxins secalonic acid D and F (EFSA, 2010; Samson et al., 2007) and is therefore ineligible for the QPS list.

7.1.4. *Beauveria bassiana*

Since the beginning of 2010, a significant number of reports (close to 300) have been published concerning *Beauveria bassiana* according to a PubMed and Web of Science search. Actually, *Beauveria bassiana* is a well-characterized entomopathogenic fungus with a high host range and a high potential in insect pest control. Several strains of *Beauveria bassiana* have been licensed for commercial use against whiteflies, aphids, thrips and numerous other insects or arthropod pests. Like any microorganism, *Beauveria bassiana* has the potential to act as an opportunistic pathogen, but as the literature studies confirms, *Beauveria bassiana* infections are extremely rare events. No new case of *Beauveria bassiana*-mediated tissue infection has been reported since the beginning of 2010. However, a recent report (Pagiotti et al., 2010) has demonstrated the occurrence of *Beauveria bassania* in a clinical environment. The exposure and health risk linked to the aerosolization of fungal pest control agents including *Beauveria bassania* has also recently been underlined (Madsen, 2011), according to the previous report of Westwood et al. (2005) on the allergens detained by *Beauveria bassania.*

Due to recognised, though limited human infection and its allergenic potential, *Beauveria bassania* is ineligible for the 2011 QPS list.

7.1.5. *Beauveria brongniartii*

During 2010 and the five first months of 2011, twelve reports dealing with *Beauveria brongniartii* have been identified through a PubMed and Web of Science survey. The majority of these focuse on the entomopathogenic potential of this fungal species. New data concerning the phylogeny and systematics of the genus *Beauveria* have also been published, with the identification of six new species in addition to *Beauveria brongniartii* and *Beauveria bassiana* (Rehner et al., 2011). In two manuscripts, the environmental risk posed by the use of *Beauveria brongniartii* as a biological control agent was considered; the low persistence in soils of this entomopathogenic fungus was confirmed (Laengle and Strasser, 2010; Scheepmaker and Butt, 2010).

No new data demonstrate the lack of toxicity associated with *Beauveria brongniartii* or clarify the toxicity of oosporein, an antifungal peptide produced by this species. Therefore, *Beauveria brongniartii* is still ineligible for QPS status.

7.1.6. *Blakeslea*

The search for new information on the genus *Blakeslea* did not retrieve any new relevant data on toxicity or toxins (EFSA, 2010). All papers were on production of lycopene from *Blakeslea* species. In light of this limited information *Blakeslea trispora* is still not recommended for QPS.

7.1.7. *Coniothyrium minitans*

Twenty-five reports concerning *Coniothyrium minitans* have been published since the beginning of 2010, according to a bibliographic survey based on PubMed and Web of Science as databases. The major part of these reports describes data that support the efficacy of *Coniothyrium minitans* for biological control of *Sclerotinia* diseases but also its potential for chitinase production and oxalic acid degradation. No new data certifying the lack of biological active secondary metabolites produced by this species has been retrieved and *Coniothyrium minitans* remains ineligible for QPS status.

7.1.8. *Duddingtonia flagrans*

Twenty-three reports on *Duddingtonia flagrans* have been published since the beginning of 2010 (using PubMed and Web of Science as bibliographic databases). Most of them deal with the nematode predatory activity of this species and illustrate the fact that *Duddingtonia flagrans* stands out as the most promising agent for the control of gastrointestinal nematodiasis in domestic animals. The environmental impact of *Duddingtonia flagrans* application was investigated in the study of Paraud et al. (2011) that led to the conclusion of an insignificant effect on the free-living soil nematodes. The recent search did however not retrieve any new relevant data on the toxicity of metabolites from this organism and *Duddingtonia flagrans* remains ineligible for QPS status.

7.1.9. *Fusarium* species

More of 1500 papers devoted to *Fusarium* have been retrieved in the time frame of search 2010-2011, using the Web of Science database. This high publishing activity illustrates the significant interest that phytopathogenic and mycotoxinogenic fungal strains of this genus still bring up.

7.1.9.1. Taxonomy

The set of available *Fusarium* species–specific primers has been largely enriched since the beginning of 2010 and the relevance of real-time PCR assay for predicting cereals contamination illustrated (Sampietro et al., 2010; Pasquali et al., 2010). A recent paper published by Park et al. (2011) describes the state of progress reached by the integrated platforms that the *Fusarium* community has built in order to facilitate strain identification, phylogenetics studies (*Fusarium* identification database or *Fusarium*-ID), comparative genomics (*Fusarium* Comparative Genomics Platform or FCGP) and knowledge sharing (*Fusarium* community platform or FCP). *Fusarium*-ID (http://isolate.fusariumdb.org/) archives more than 5500 markers (a number that continuously increases), representing over than 200 species. Sequences at three loci (EF-1α, RNA polymerase RPB1 and RPB2) are available for all the described phylogenetic species that can serve as relevant tools to help identify new isolates.

7.1.9.2. Biosynthetic pathways of *Fusarium* mycotoxins and their regulation

Although more than 300 papers dealing with *Fusarium* mycotoxins have been published since the beginning of 2010 (according to a Web of Science search), no significant progress has been made in elucidating the regulatory mechanisms that induce or repress mycotoxins production. The most relevant data concern the identification of factors that, in *planta*, are likely to modulate toxins accumulation, such as polyamines for trichothecenes (Gardiner et al., 2010) and oxylipins for fumonisins and aflatoxins (Christensen and Kolomiets, 2011). A recent paper describes also cobalt chloride as an efficient enhancer of *in vitro* trichothecenes production, and as a useful tool to investigate regulatory mechanisms (Tsuyuki et al., 2011).

7.1.9.3. Emerging *Fusarium* toxins

Enniatins, beauvericin, moniformin and fusaproliferin have been the subject of several papers (approximately 15 for each toxin) since the beginning of 2010 (according to a Web of Science search). Definition of 'Taqman' assays to quantify the producers, elucidation of the biosynthetic pathway and required genes, investigation of their toxic effects are the main topics developed in these papers. There is also an ongoing debate on the question of a higher prevalence of these emerging toxins linked to climate–change effects (Magan et al., 2011).

7.1.10. *Gliocladium catenulatum*

The current name in use for *Gliocladium catenulatum* is *Clonostachys rosea* f. *catenulata* and the taxonomic relationship as well as nomenclature is described in detail (EFSA, 2009). Bertinetti et al. (2010) report the production of a new antimicrobial compound, which is active against the honey bee pathogen *Paenibacillus larvae*, but showed no activity against *Bacillus subtilis, Staphylococcus aureus* and *Escherichia coli* (Bertinetti et al., 2010). No information on lack of toxins or toxicity against mammals is reported, therefore this species cannot be proposed for the QPS list.

7.1.11. *Lecanicillium muscarium*

All reports from a Web of Science search deal with the pathogenicity against insects. No new data on toxins or safety has been published, therefore this species cannot be proposed for the QPS list.

7.1.12. *Metarhizum anisopliae*

Many of the nearly 300 reports on *Metarhizum anisopliae* retrieved by a search in Web of Science deal with the production of metabolites and genetic and physiological regulation of the metabolism, as well as the toxicity towards insects. However, a recent report demonstrates cytotoxic effects of conidia in the lungs of mice (Anand and Tiwary, 2010) and a case of corneal ulcer in a child (Motley et al., 2011). A recent review of the toxins of *Metarhizium anisopliae* does not bring forward any general lack of toxicity (Schrank and Vainstein, 2010). Therefore *Metarhizum anisopliae* cannot be proposed for the QPS list.

7.1.13. *Paecilomyces lilacinus*

Since the beginning of 2010, according to a PubMed and Web of Science search, more than 70 publications dealing with *Paecilomyces lilacinus* have been published. Among these, several reports support the potential of this species as an agent for the control of plant-parasitic nematodes. In 10 papers, human and animal invasive infection events linked to *Paecilomyces lilacinus* (or related species) are described: four cases of *Paecilomyces keratitis* (Yildiz et al., 2010; Pei-Chen et al., 2010), one of invasive fungal rhinitis (Ciecko et al., 2010), a case of dog dermatomycosis (Han et al., 2010) and one of fungal endophtalmitis in an immunocompetent patient (Anita et al., 2011). According to two supplementary papers (Rosmaninho et al., 2010; Houbraken et al., 2010), *Paecilomyces lilacinus* is considered as one of the most frequently encountered emerging causative agents leading to opportunistic infection, especially in immunocompromised and transplant patients. Based on this, *Paecilomyces lilacinus* cannot be proposed for the QPS list.

7.1.14. *Penicillium* species

For the *Penicillium* species, *Penicillium camemberti, Penicillium chrysogenum, Penicillium funiculosum, Penicillium nalgiovense* and *Penicillium roqueforti*, no new information on the lack of toxicity or toxins have been retrieved. The reports deal with production of the specific products or food spoilage problems.

7.1.15. *Phlebiopsis gigantea*

The recent search in Web of Science did not reveal any new information of the general lack of toxicity of *Phlebiopsis gigantea*. The knowledge concerning the capacity of *Phlebiopsis gigantea* to produce biological active secondary metabolites remains therefore insufficient and this species cannot be proposed for the QPS list.

7.1.16. *Pseudozyma flocculosa*

The recent search for new information on metabolites or (lack of) toxicity did not retrieve any new relevant data for this organism. The body of knowledge is insufficient to propose *Pseudozyma flocculosa* for the QPS list.

7.1.17. *Pythium oligandrum*

Seven reports have focused on *Pythium oligandrum* since the beginning of 2010, according to a bibliographic survey using PubMed and Web of Science as databases. These reports support the ability of this hyperparasite to colonize other pathogenic fungi in and around seeds and the rhizosphere of treated plants. One report clarifies the mechanisms by which *Pythium oligandrum* is also able to enhance plant defence reactions (Masunaka et al., 2010). When the key word pythiosis was used, 17 reports, all associated with the *Pythium insidiosum* species, were retrieved.

No new data demonstrated the lack of toxicological or pathogenic effects of *Pythium oligandrum* in mammals. Therefore, *Pythium oligandrum* is still ineligible for QPS status.

7.1.18. *Trichoderma* species

More than 900 papers have been published since the beginning of 2010 (according to a Web of Science search). The most frequently reported results concern the use of some strains belonging to this genus for enzymes production, mainly enzymes involved in plant cell wall degradation.

7.1.18.1. Taxonomy

The taxonomy of *Trichoderma* has been improved by a handful of papers and monographs that clarifies the species delimitation in some sections of this genus. The new taxonomic schemes do not have any impact on taxonomic designations of species notified to EFSA.

7.1.18.2. Trichoderma asperellum

This species was assessed this year for the first time. *Trichoderma asperellum* strains are commonly isolated from soil and decomposing matter, occurrence of marine strains is also reported. According to a Web of Science and PubMed searches, the major part of the more recently published reports that deals with *Trichoderma asperellum* illustrates its efficiency as a mycoparasitic biocontrol agent. *Trichoderma asperellum* is described as an antagonist of many soil borne fungal plant pathogens such as *Sclerotinia* spp., *Thielaviopsis paradoxa* (Wijesinghe et al., 2010), *Fusarium oxysporum* and of root-knot nematodes (Affokpon et al., 2011). The use of *Trichoderma asperellum* as a method of bioremediation for soil, sediment or water contaminated with heavy metals has also been investigated and the uptake capacity of *Trichoderma asperellum* for arsenic was illustrated (Su et al., 2010). In one of the retrieved report, the production of neurotoxic metabolites by marine-derived strains of *Trichoderma asperellum* was demonstrated, the structures of six peptaibols called asperelines A-F were elucidated (Ren et al., 2009).

Considering the capacity detained by some strains of *Trichoderma asperellum* to produce biological active compounds, each strain should be investigated in detail, which makes *Trichoderma asperellum* ineligible for QPS status.

7.1.18.3. *Trichoderma longibrachiatum*

This species was assessed this year because a notification relating to enzyme production was received. *Trichoderma longibrachiatum* is one of the most studied filamentous fungi for its potential to produce plant cell wall-degrading enzymes (xylanase, cellulase, glucanase) with a high diversity of industrial applications: pulp and paper industry, green chemistry, biofuel, food and feed industry. Among the 23 reports devoted to *Trichoderma longibrachiatum* that have been published since the beginning of 2010 (PubMed and Web of Science searches), half of them concern the efficient use of *Trichoderma longibrachiatum* for enzyme production. *Trichoderma longibrachiatum* is a very common fungus in environmental samples from all over the world with also the occurrence of marine strains. Production of peptaibols such as longibrachin-A-I by these marine-related strains is well documented (Mohamed-Benkada et al., 2006). These toxic metabolites, that exhibit neurotoxicity by forming pores in neuronal membranes, were also recently demonstrated to enhance the toxicity of domoic acid, a neurotoxic phycotoxin (Ruiz et al., 2010). Moreover, *Trichoderma longibrachiatum* shows increasing medical importance as an opportunistic human pathogen particularly in immunocompromised and immunosuppressed patients. *Trichoderma longibrachiatum* is described as the causal agent in the majority of reported *Trichoderma* mycoses. One of the more recently reported clinical case related to *Trichoderma longibrachiatum* was the case of an infection in a renal transplant recipient in Tunisia (Trabelsi et al., 2010). According to the previous comments, *Trichoderma longibrachiatum* cannot be eligible for QPS status.

7.1.18.4. Trichoderma viride

Trichoderma viride was re-assessed this year because a notification for enzyme production was received. *Trichoderma viride* is a well-known cellulose-degrading fungus and a well studied fungus for its ability to produce large amounts of cellulolytic enzymes. However, according to Cvetnic and Pepeljnjak (1997), some strains of *Trichoderma viride* have the ability to produce a highly toxic metabolite, the diacetooxyscirpenol. There is no solid proof that their observation is true. Their strains were unnumbered and have not been kept in a collection for re-evaluation and their chemical detection is by TLC which is highly insufficient for the trichothecenes such as diacetoxyscirpenol. A clarification of production of trichothecenes by *Trichoderma* species was published later (Nielsen et al., 2005) where it was demonstrated that the trichothecene producer should be named *Trichoderma brevicompactum*. Later, another new species, *Trichoderma arundinaceum*, was also found to produce trichothecenes (Degenkolb et al., 2008).

As already concluded in previous EFSA Opinions (EFSA, 2009; 2010), *Trichoderma viride* cannot be granted QPS status as this and other *Trichoderma* species do produce the highly biological active peptaibols, which are small peptides (15-20 amino acids) containing α-aminoisobutyric acid.

According to this potentiality to produce mycotoxins, *Trichoderma viride* cannot be recommended for the QPS list.

7.1.19. *Verticillium alboatrum*

A bibliographic survey using PubMed and Web of Science as databases indicates that 26 reports have been recently devoted to *Verticillium alboatrum* (since the beginning of 2010). The pathogenicity of this species in relation to wilt diseases of vegetable crops was the focus of these 26 reports. No new data have been published since the beginning of 2010 clarifying the toxicity of alboatrin and VDtoxins, two phytotoxins produced by *Verticillium albo-atrum*. The body of knowledge remains therefore very limited, and this species cannot be proposed for the QPS list.

7.1.20. Conclusions on filamentous fungi

In the 2010 QPS opinion, it was concluded that filamentous fungi cannot be proposed for inclusion on the QPS list owing to three main rationales: the frequent occurrence of inaccuracies and inconsistencies in fungal species identification, the insufficient knowledge concerning the regulation mechanisms underlying the production of fungal metabolites and the poor knowledge concerning the toxic impact of fungal secondary metabolites. Although numerous data, published since the 2010 QPS opinion, have contributed to partially fulfil these gaps of knowledge, too many unknowns remain in 2011 to allow a filamentous fungus to be qualified as QPS.

The extensive literature search that has been performed to establish this 2011 QPS opinion has actually underlined the tremendous progress in filamentous fungus knowledge recently achieved but has also illustrated an increased activity in the discovery of new mycotoxins, designed as emerging mycotoxins.

7.2. Viruses used for plant protection

7.2.1. Potyviridae

Viruses belonging to the family Potyviridae are used for cross protection purposes, i.e. the application of mild strains of a virus protects the crop against strains of the virus giving severe symptoms. Their potential effects on animals and/or humans, when applied to food or feed, were reviewed and assessed, and the results were published in the EFSA Opinion on QPS 2009 (EFSA, 2009) and 2010 (EFSA, 2010). It was concluded that there was no scientific or other evidence that potyviruses have any negative effect on animals and humans to date. In addition, the familiarity principle was taken into consideration as well in that these viruses have been part of the food and feed for animals and humans since plant material was part of the food package. Hence it was agreed that the family Potyviridae is the highest taxonomic unit, which should receive QPS status. Since this last major review, no new information which would compromise the conclusion drawn in 2010 has appeared. Furthermore, evidence was found (Kuiper et al., 2001) that the major products of potyviruses that are used in cross protection (zucchini yellows mosaic virus) were specifically evaluated for their possible toxic effect on animals when expressed in transgenic plants. The sequences of these products, the coat proteins of watermelon mosaic virus 2 and zucchini yellows mosaic virus, were compared to databases of known proteinaceous toxins, but none of these showed any homology to potential known mammalian protein toxins (Health Canada, 1999). In conclusion, viruses belonging to the Potyviridae family should remanin to receive QPS status.

7.2.2. Baculoviridae

Viruses belonging to the family Baculoviridae and their potential effects on animals and humans, when applied to food or feed, were extensively reviewed and the results were published in the EFSA Opinion on QPS 2009 (EFSA, 2009) and 2010 (EFSA, 2010). It was concluded that there was no scientific or other evidence that baculoviruses have any negative effect on animals and humans to date when used appropriately as a biocontrol agent. In addition the familiarity principle was taken into consideration as well in that these viruses have been extensively used for over five decades as biocontrol agents of insect pests without any report describing a negative effect on humans or animals. Furthermore, baculoviruses frequently appear in nature as disease agent of insect caterpillar, without a negative report on human or animal health. The OECD already concluded that baculoviruses were safe to use for products intended for human consumption (Anonymus, 2002).

Hence it was agreed that the family Baculoviridae is the highest taxonomic unit should receive QPS status in the registration process (EFSA 2009; EFSA 2010).

Since the last major review, no new information which would compromise the conclusion drawn in 2009 and 2010 has appeared. Further support for the safety of baculoviruses is taken from the fact that a number of baculovirus-derived products (recombinant proteins) have been registered and reached the market, such as vaccines against cervical cancer (Harper, 2009; Szarewski, 2010), porcine circovirus (Fort et al., 2009) and immunotherapeutics for prostate cancer (Kantoff et al., 2010).

A matter of contention could be the observation that the budded virus (BV) phenotype of baculoviruses, that is responsible for the systemic infection of insect larvae, is able to infect mammalian cells and tissues to serve as a gene delivery vehicle for gene therapy (Hu, 2008; Rivera-Gonzalez et al., 2011). BV infection and replication is very specific for insects only. The infection (entry) by the BV form of baculoviruses of mammalian cells is very artificial and will never happen in natural situations. In addition, replication of baculovirus in mammalian cells has never been shown. Furthermore, the *in vivo* complement system in mammalian blood eliminates the BV form of the virus as soon as it enters, but does not block gene delivery (Hofmann and Strauss, 1998). The baculovirus phenotype present in the baculovirus capsule, as it is used for biocontrol, cannot infect mammalian cells; moreover the baculovirus capsules will pass the digestive system unaffected.

When appropriately used, baculovirus in conjunction with food and feed will impose no harm on animal or human health.

Apart from the intrinsic biological features of baculoviruses and their inherent safety for humans and other vertebrates, a point of attention to note is the fact that these viruses have to be produced in animals (insects) and have to be formulated to stick to plant material and to protect the virus against UV damage. Microbial contaminants, allergenicity and toxicity of additives are among the agents, which could affect human and animal health. This concerns the formulation and does not contradict the recommendation to include the Baculoviridae on the QPS list. Regulation on the microbiological contaminants in baculovirus preparations is in place as part of the registration requirements (Rochon et al., 2009).

Table 1: The 2011 updated list of QPS recommended biological agents

Gram-Positive Non-Sporulating Bacteria			
Species			**Qualifications ***
Bifidobacterium adolescentis *Bifidobacterium animalis*	*Bifidobacterium bifidum* *Bifidobacterium breve*	*Bifidobacterium longum*	
*Corynebacterium glutamicum***			QPS recommendation only when the species is used for amino acid production.
Lactobacillus acidophilus *Lactobacillus amylolyticus* *Lactobacillus amylovorus* *Lactobacillus alimentarius* *Lactobacillus aviaries* *Lactobacillus brevis* *Lactobacillus buchneri* *Lactobacillus casei* *** *Lactobacillus cellobiosus* *Lactobacillus coryniformis* *Lactobacillus crispatus* *Lactobacillus curvatus* *Lactobacillus delbrueckii*	*Lactobacillus farciminis* *Lactobacillus fermentum* *Lactobacillus gallinarum* *Lactobacillus gasseri* *Lactobacillus helveticus* *Lactobacillus hilgardii* *Lactobacillus johnsonii* *Lactobacillus kefiranofaciens* *Lactobacillus kefiri* *Lactobacillus mucosae* *Lactobacillus panis* *Lactobacillus collinoides*	*Lactobacillus paracasei* *Lactobacillus paraplantarum* *Lactobacillus pentosus* *Lactobacillus plantarum* *Lactobacillus pontis* *Lactobacillus reuteri* *Lactobacillus rhamnosus* *Lactobacillus sakei* *Lactobacillus salivarius* *Lactobacillus sanfranciscensis*	
Lactococcus lactis			
Leuconostoc citreum	*Leuconostoc lactis*	*Leuconostoc mesenteroides*	
	Oenococcus oeni		
Pediococcus acidilactici	*Pediococcus dextrinicus*	*Pediococcus pentosaceus*	
Propionibacterium freudenreichii	*Propiobacterium acidopropionici*		
Streptococcus thermophilus			
Bacillus			
Species			**Qualifications***
Bacillus amyloliquefaciens *Bacillus atrophaeus* *Bacillus clausii* *Bacillus coagulans* *Bacillus fusiformis*	*Bacillus lentus* *Bacillus licheniformis* *Bacillus megaterium* *Bacillus mojavensis*	*Bacillus pumilus* *Bacillus subtilis* *Bacillus vallismortis* *Geobacillus stearothermophilus*	Absence of toxigenic activity.

* Generic qualification for all QPS bacterial taxonomic units: the strains should not harbour any acquired antimicrobial resistance genes to clinically relevant antibiotics.

** *Brevibacterium lactofermentum* is a synonym of *Corynebacterium glutamicum*

*** The previously described species "*Lactobacillus zeae*" has been included in the species *Lactobacillus casei*

Table 1 Continued: The 2011 updated list of biological agents recommended for QPS

Yeasts[14]			
Species			**Qualifications**
Debaryomyces hansenii			
Hanseniaspora uvarum			
Kluyveromyces lactis	*Kluyveromyces marxianus*		
Komagataella pastoris *Lindnera jadinii* *Pichia angusta*			QPS applies only when the species is used for enzyme production
*Saccharomyces bayanus*****	*Saccharomyces cerevisiae*†****	*Saccharomyces pastorianus*****	
Schizosaccharomyces pombe			
*Wickerhamomyces anomalus*****			QPS applies only when the species is used for enzyme production
Xanthophyllomyces dendrorhous (imperfect form *Phaffia rhodozyma)*			
Virus			
Family			
Potyviridae	*Baculoviridae*		

****Absence of resistance to antimycotics used for medical treatment of yeast infections in cases where viable cells are added to the food or feed chain. In the case of *Saccharomyces cerevisiae* this qualification applies for yeast strains able to grow above 37 °C.

† *S. cerevisiae*, subtype *boulardii* is contraindicated for patients of fragile health, as well as for patients with a central venous catheter in place.

14 Yeast synonyms commonly used in the feed/food industry
Wickerhamomyces anomalus: synonym *Hansenula anomala*, *Pichia anomola, Saccharomyces anomalus*
Lindnera jadinii: anamorph *Candida utilis*; synonyms *Pichia jadinii*, *Hansenula jadinii*, *Torulopsis utilis*
Saccharomyces cerevisiae synonym *S. boulardii*
Saccharomyces pastorianus: synonym of Saccharomyces carlsbergensis
Komagataella pastoris: synonym *Pichia pastoris*

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Answer to the terms of reference (ToR):

ToR1: *Preparation of an update of the list of biological agents notified to EFSA for safety assessment. This should be a starting point for identifying new taxonomic units for review under the QPS assessment. Only those taxonomic units relevant to current legal requirements in the context of notification to EFSA for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products shall be included.* The list was completed with the notifications received where applicable by EFSA Panels and Units since the last review.

ToR2*: Annual review of the list of biological agents recommended for the QPS list. Where appropriate new taxonomic units should be assessed for their suitability for an inclusion in the QPS list, and taxonomic units previously assessed should be reviewed where new information has become available. The information provided in the previous opinion should be updated where appropriate.*

All taxonomic units previously recommended for the QPS list were confirmed. The notifications were assessed and no new recommendations for the QPS list were made.

An assessment of three new bacterial species (*Ensifer adhaerens* and *Ensifer fredii*, *Ketogulonicigenium vulgare*, *Clostridium butyricum*), a new yeast species (*Trichosporon mycotoxinivorans*) and several additional fungi species (*Ampelomyces quisqualis*, *Ashbya gossypii*, *Aspergillus aculeatus*, *Trichoderma asperellum*, *Trichoderma longibrachiatum* for enzyme production, *Trichoderma viride* for enzyme production) was performed but these species were not included on the QPS list.

Phaffia rhodozyma the imperfect form of *Xanthophyllomyces dendrorhous* was included on the QPS recommended list. In accordance with the most recent taxonomic revision of yeasts, *Pichia jadinii* was changed to *Lindnera jadinii*.

The information of the previous opinion was updated for the taxonomic units on the QPS list.

ToR3 and 4: *Review and update of knowledge concerning antimicrobial resistance in taxonomic units recommended for the QPS list. Review of the qualifications for taxonomic units included on the QPS recommended list.*

The information of the previous opinion was updated for bacteria and the qualification on antimicrobial resistance was confirmed.

For the yeast the knowledge on antimycotic resistance was updated and the qualification ‘on absence of resistance to antimycotics used for medical treatment of yeast infections’ was complemented by the sentence ‘in the case of *Saccharomyces cerevisiae* this qualification applies for yeast strains able to grow above 37 °C’. This qualification is only relevant if viable yeasts are intentionally introduced into the food chain and it was restricted to those yeast species for which information on antifungal susceptibility exists.

ToR5: *Review of the body of knowledge for filamentous fungi and enterococci.*

The knowledge of filamentous fungi notified for EFSA was updated. Although numerous data, published since the 2010 QPS opinion, have contributed to partially fulfil gaps of knowledge, too many unknowns remain in 2011 to allow a filamentous fungus to be qualified as QPS.

Enterococci cannot be considered for the QPS list based on the current scientific knowledge.

RECOMMENDATIONS

While recent findings do not warrant any reconsideration of the QPS status of lactic acid bacteria (LAB) and *Bacillus* species, further studies on both human and veterinary clinical isolates particularly from cases where there have been no predisposing factors, should be considered to find out any specific factors that might contribute to the pathogenicity.

More data on minimum inhibitory concentrations (MIC) for therapeutic antimicrobials and guidelines for the interpretation are needed in general for all bacteria used for food and feed purposes.

More information on the antifungal susceptibility of yeasts frequently introduced into the food and feed chain is needed.

Concerning fungi, the same recommendations as those issued from the 2010 QPS opinion remain valuable. Progresses have to be achieved to attain three main objectives:

(i) the definition and use of standardized methods to allow a correct identification of fungal species

(ii) an accurate establishment of the metabolic profile for each considered species and an increased knowledge of the factors controlling the production of fungal toxic metabolites

(iii) an increased knowledge of the toxicological impact of fungal secondary metabolites.

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APPENDIX

A. MICROBIAL SPECIES FROM PREVIOUS NOTIFICATIONS AND AS NOTIFIED TO EFSA

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
	Bacteria			
FEEDAP	*Actinoplanes utahensis*	Production of acarbose	EFSA-Q-2007-172 The EFSA Journal (2008) 839, 1-40 www.efsa.europa.eu/en/scdocs/scdoc/839.htm	No body of knowledge, therefore not appropriate for QPS (EFSA, 2008). Full safety assessment was performed in FEEDAP Opinion.
FEEDAP	*Actinomadura yumaensis*	Production of maduramicin ammonium	EFSA-Q-2008-757 The EFSA Journal (2011) 9(1):1954 www.efsa.europa.eu/en/efsajournal/doc/1954.pdf	*Actinomadura yumaensis* produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)
FEEDAP	*Alcaligenes acidovorans* = *Ralstonia* sp.	Biomass for animal feed	EFSA-Q-2004-171 The EFSA Journal (2005) 230, 1-6 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620784006.htm	No body of knowledge, therefore not appropriate for QPS (EFSA, 2008). Full safety assessment was performed in FEEDAP Opinion.
FEEDAP	*Bacillus amyloliquefaciens*	Feed additive	EFSA-Q-2007-190 The EFSA Journal (2008) 773, 1-13 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902039267.htm EFSA-Q-2009-00825 EFSA Journal 2010;8(12):1918 [2 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1918.htm EFSA-Q-2011-00389 (In progress)	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Bacillus amyloliquefaciens*	Production of Enzyme	EFSA-Q-2007-0020 (GMM): www.efsa.europa.eu/en/efsajournal/pub/1156.htm and related opinions: EFSA-Q-2007-112: www.efsa.europa.eu/en/efsajournal/pub/1154.htm EFSA-Q-2009-00470: www.efsa.europa.eu/en/efsajournal/pub/1949.htm Other applications EFSA-Q-2010-01295 (under consideration) EFSA-Q-2010-01297 (under consideration) FAD-2010-0367 (formal mandate to arrive)	
Pesticides	*Bacillus amyloliquefaciens* subspecies plantarum strain D747	Plant protection product	No Draft Assessment Report received – no EFSA Question yet	
FEEDAP	*Bacillus brevis* = *Aneurinibacillus* and *Brevibacillus species* Strains from *B. brevis* are now mostly *Brevibacillus* species and some are *Aneurinibacillus* species	Biomass for animal feed	EFSA-Q-2004-171 The EFSA Journal (2005) 230, 1-6 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620784006.htm	No sufficient body of knowledge and safety concern because of antibiotic production. Therefore not appropriate for QPS (EFSA, 2008). It will no longer be assessed for the QPS list unless new notification to EFSA (2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Bacillus cereus var. toyoi* = *B. cereus*	Feed additive	EFSA-Q-2003-086 The EFSA Journal (2004) 62, 1-5 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783486.htm EFSA-Q-2005-021 The EFSA Journal (2005) 288, 1-7 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783657.htm EFSA-Q-2006-037 The EFSA Journal (2007) 458, 1-9 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620781828.htm EFSA-Q-2007-090 The EFSA Journal (2008) 549, 1-11 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178647331659.htm EFSA-Q-2008-287 The EFSA Journal (2008) 913, 1-13 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902299515.htm EFSA-Q-2010-01095 (in progress) EFSA-Q-2011-00832 (in progress)	QPS status inapplicable for the group of *B. cereus* strains (see EFSA opinion 2007, Appendix B, EFSA, 2008). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Bacillus coagulans*	Feed additive		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Bacillus firmus = Brevibacillus agri*	Biomass for animal feed	EFSA-Q-2004-171 The EFSA Journal (2005) 230, 1-6 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620784006.htm	No body of knowledge, therefore not appropriate for QPS (EFSA 2008). It will no longer be assessed for the QPS list unless new notification to EFSA (2010).
Pesticides	*Bacillus firmus I-1582*	Plant protection product	New active substance. Draft assessment report received. No EFSA question number yet	A reassessed of this species will be carried in the QPS 2012 review.
FEEDAP	*Bacillus lentus*	Feed additive		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
FEEDAP	*Bacillus lentus*	Production of Enzyme	EFSA-Q-2006-004: www.efsa.europa.eu/en/efsajournal/doc/412.pdf	
SCF Opinion 22 June 2000	*Bacillus licheniformis*	Production of b-cyclodextrin (food additive carrier and stabiliser of food flavours, food colours and some vitamins)		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
FEEDAP	*Bacillus licheniformis*	Production of Enzyme	EFSA-Q-2005-090: www.efsa.europa.eu/en/efsajournal/pub/351.htm EFSA-Q_2006-0181: www.efsa.europa.eu/en/efsajournal/pub/451.htm EFSA-Q-2010-00139 (GMM, in progress) EFSA-Q-2008-431 (GMM): www.efsa.europa.eu/en/efsajournal/pub/1185.htm	

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Bacillus licheniformis*	Feed additive	EFSA-Q-2006-136 (adopted) EFSA Journal 2011;9(9):2356 [10 pp.]. http://www.efsa.europa.eu/en/efsajournal/pub/2356.htm EFSA-Q-2007-166 (in progress) EFSA-Q-2009-00970 (in progress) EFSA-Q-2009-00680 (in progress)	Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
FEEDAP	*Bacillus megaterium*	Production of vitamin C	EFSA-Q-2010-01290 (in progress)	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
FEEDAP	*Bacillus pumilus*	Feed additive		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
Pesticides	*Bacillus pumilus* strain QST 2808	Plant protection product	No Draft Assessment Report received – no EFSA Question yet.	

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Bacillus subtilis*	Feed additive	EFSA-2003-008 www.efsa.europa.eu/en/efsajournal/pub/6.htm EFSA-Q-2004-174 www.efsa.europa.eu/en/efsajournal/pub/272.htm EFSA-Q-2005-150 www.efsa.europa.eu/en/scdocs/scdoc/336.htm EFSA-Q-2005-237 The EFSA Journal (2006) 336, 1-15 www.efsa.europa.eu/en/scdocs/scdoc/406.htm EFSA-Q-2006-136 (adopted) EFSA Journal 2011;9(9):2356 [10 pp.]. http://www.efsa.europa.eu/en/efsajournal/pub/2356.htm EFSA-Q-2007-166 (in progress) EFSA-Q-2007-040 The EFSA Journal (2007) 543, 1-8 www.efsa.europa.eu/en/scdocs/scdoc/543.htm EFSA-Q-2008-473 EFSA Journal 2009; 7(9):1314 www.efsa.europa.eu/en/scdocs/scdoc/1314.htm EFSA-2008-771 www.efsa.europa.eu/en/efsajournal/pub/2375.htm EFSA-Q-2009-00533 EFSA Journal 2010; 8(1):1426 www.efsa.europa.eu/en/scdocs/scdoc/1426.htm	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Bacillus subtilis*	Feed additive	EFSA-Q-2009-00680 (in progress) EFSA-Q-2009-00525 (In progress) EFSA-Q-2010-00814 EFSA Journal 2010;8(10):1867 www.efsa.europa.eu/en/scdocs/scdoc/1867.htm EFSA-Q-2010-001151 EFSA Journal 2011;9(3):2112 www.efsa.europa.eu/en/efsajournal/pub/2112.htm EFSA-Q-2010-01150 EFSA Journal 2011;9(3):2114 www.efsa.europa.eu/en/efsajournal/pub/2114.htm	
FEEDAP	*Bacillus subtilis*	Production of vitamin B2	EFSA-Q-2010-00991 (GMM, in progress) EFSA-Q-2010-01319 (GMM, in progress)	
FEEDAP	*Bacillus subtilis*	Production of enzyme	FAD-2010-0367 (formal mandate to arrive) EFSA-Q-2007-0020: www.efsa.europa.eu/en/efsajournal/pub/1156.htm and related opinions: EFSA-Q-2007-112: www.efsa.europa.eu/en/efsajournal/pub/1154.htm EFSA-Q-2009-00470: www.efsa.europa.eu/en/efsajournal/pub/1949.htm Other applications: EFSA-2010-01298 (GMM in progress)	
Pesticides	*Bacillus subtilis* Strain QST 713	Plant protection product	EFSA-Q-2008-492 (In progress)	Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Pesticides	*Bacillus* subsp. *thuringiensis aizawai* (strains ABTS 1857 and GC-91) = *Bacillus thuringiensis* serovar aizawai	Plant protection product	EFSA-Q-2009-00121 (In progress) EFSA-Q-2009-00247 (In progress) [www.epa.gov/opp00001/biopesticides/ ingredients/factsheets/factsheet_006494.htm]	Already considered as not appropriate for QPS (see EFSA opinion, 2007). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
Pesticides	*Bacillus* subsp. *thuringiensis israelensis* (serotype H-14), strain AM 6552 = *Bacillus thuringiensis* serovar israelensis	Plant protection product	EFSA-Q-2009-00122 (in progress) EFSA-Q-2009-00248 (In progress) [www.epa.gov/opp00001/biopesticides/ingredient s/factsheets/factsheet_006476.htm]	Already considered as not appropriate for QPS (see EFSA, 2007). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
Pesticides	*Bacillus* subsp. *thuringiensis kurstaki* (strains ABTS 351, PB 54, SA11, SA 12, EG 2348) = *Bacillus thuringiensis* serovar kurstaki	Plant protection product	EFSA-Q-2009-00123 (in progress) EFSA-Q-2009-00249 (In progress) [www.epa.gov/opp00001/biopesticides/ ingredients/factsheets/factsheet_006452.htm]	Already considered as not appropriate for QPS (see EFSA, 2007). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
Pesticides	*Bacillus* subsp. *thuringiensis tenebrionis* (strain NB176 (TM 141)) = *Bacillus thuringiensis* serovar tenebrionis	Plant protection product	EFSA-Q-2009-00124 (in progress) EFSA-Q-2009-00250 (In progress)	Already considered as not appropriate for QPS (see EFSA, 2007). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Bifidobacterium animalis*	Feed additive	EFSA-Q-2006-00169 (In progress) EFSA-Q-2009-00823 (In progress) EFSA-Q-2009-00817 (In progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Bifidobacterium longum*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
GMO	*Brevibacterium lactofermentum* =*Corynebacterium glutamicum*	Dried killed biomass for feed	EFSA-Q-2007-157 (Additional data requested)	The recipient species is QPS for production purposes only, but not for this application, therefore not appropriate for QPS (EFSA, 2008 opinion)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Clostridium butyricum*	Feed additive	EFSA-Q-2008-303 The EFSA Journal (2009) 1039, 1-6 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902496474.htm EFSA-Q-2010-00140 EFSA Journal 2011;9(1):1951 [15 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1951.htm	No history of use, possible production of botulinum toxins, therefore not appropriate for QPS (EFSA, 2008)
FEEDAP	*Corynebacterium glutamicum*	Production of L-Arginin	EFSA-Q-2006-031 The EFSA Journal (2007) 473, 1-19 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620781637.htm	QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)
FEEDAP	*Corynebacterium glutamicum*	Production of L-lysine production	EFSA-Q-2010-01301 (in progress) EFSA-Q-2010-01036 (in progress)	QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)
FEEDAP	*Corynebacterium glutamicum*	Production of L-Tryptophan	EFSA-Q-2010-01026 (in progress)	QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)
FEDDAP	*Ensifer adhaerens*	Production of vitamin B12	Formal mandate still to arrive	Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge
FEEDAP	*Ensifer fredii*	Production of vitamin B12	Formal mandate still to arrive	Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge
FEEDAP	*Enterococcus faecium*	Feed additive	EFSA-Q-2003-087 The EFSA Journal (2005) 207, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/207.htm EFSA-Q-2004-001 The EFSA Journal (2004) 51, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/51.htm EFSA-Q-2004-006 The EFSA Journal (2004) 138, 1-7 www.efsa.europa.eu/en/efsajournal/pub/138.htm EFSA-Q-2004-027 The EFSA Journal (2004) 120, 1-4	No taxonomical unit within *Enterococcus* can be considered as free of infectious strains. Therefore no recommendation for QPS status (EFSA, 2007, 2008, 2009, 2010). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available (2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
			www.efsa.europa.eu/en/scdocs/scdoc/120.htm EFSA-Q-2004-096 The EFSA Journal (2005) 206, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/206.htm EFSA-Q-2005-020 The EFSA Journal (2006) 335, 1-10 www.efsa.europa.eu/en/scdocs/scdoc/335.htm EFSA-Q-2006-061 The EFSA Journal (2007) 440, 1-9 www.efsa.europa.eu/en/scdocs/scdoc/440.htm EFSA-Q-2006-318 EFSA Journal 2009; 7(11):1379 www.efsa.europa.eu/en/scdocs/scdoc/1379.htm EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/912.htm EFSA-Q-2006-169 (in progress) EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/efsajournal/pub/912.htm EFSA-Q-2007-033 The EFSA Journal (2007) 521, 1-8 www.efsa.europa.eu/en/scdocs/scdoc/521.htm EFSA-Q-2008-289 The EFSA Journal (2009) 990, 1-12 www.efsa.europa.eu/en/scdocs/scdoc/990.htm	

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
			EFSA-Q-2008-471 (in progress) EFSA-Q-2008-422 EFSA Journal 2010; 8(7):1661 [13 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1661.htm EFSA-Q-2009-00679 (In progress) EFSA-Q-2009-00969 (In progress) EFSA-Q-2009-00823 (In progress) EFSA-Q-2009-00202 (In progress) EFSA-Q-2010-00070 EFSA Journal 2010; 8(6): 1636 [5 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1636.htm EFSA-Q-2010-00009 (in progress) EFSA-Q-2010-00071 (in progress) EFSA-Q-2011-00203 (in progress)	
FEEDAP	*Enterococcus mundtii*	Feed additive		No taxonomical unit within *Enterococcus* can be considered as free of infectious strains. Therefore no recommendation for QPS status (EFSA opinion, 2007)
GMO	*Escherichia coli*	Dried killed biomasses for feed	EFSA-Q-2008-412a and EFSA-Q-2008-669a (Additional data requested)	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Escherichia coli*	Dried killed biomasses for feed	EFSA-Q-2008-412b and EFSA-Q-2008-669b (Additional data requested)	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Escherichia coli*	Feed additive L-threonine production	EFSA-Q-2010-01067 (In progress); EFSA-Q-2010-01034 (In progress); EFSA-Q-2010-1314 (In progress); EFSA-Q-2010-01305 (In progress)	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Escherichia coli*	Feed additive L-tryptophan production	EFSA-Q-2010-01310, (In progress); EFSA-Q-2010-01026 (In progress); EFSA-Q-2010-01306 (In progress)	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Escherichia coli*	Feed additive (horses)	EFSA-Q-2005-167 The EFSA Journal (2009) 989, 1-14 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902391773.htm	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Eubacterium* sp. DSM 11798	Reduce toxicity of mycotoxins	EFSA-Q-2003-052 The EFSA Journal (2005) 169, 1-14 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620782757.htm	No body of knowledge. Already given a negative assessment by FEEDAP. Not appropriate for QPS (EFSA opinion 2008)
FEEDAP	*Ketogulonicigenium vulgare*	Production of vitamin C	EFSA-Q-2011-00250 (in progress)	Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge
FEEDAP	*Lactobacillus acidophilus*	Feed additive	EFSA-Q-2003-115 The EFSA Journal (2004) 119, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/119.htm EFSA-Q-2003-055 The EFSA Journal (2004) 52, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/52.htm EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/912.htm EFSA-Q-2008-377 (in progress) EFSA-Q-2010-00071 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus amylolyticus*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Lactobacillus amylovorans*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus brevis*	Feed additive	EFSA-Q-2010-01304 (under consideration) EFSA-Q-2011-00382 (in progress) EFSA-Q-2011-00385 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacilllus buchneri*	Feed additive	EFSA-Q-2010-01276 EFSA Journal 2011;9(4):2138 www.efsa.europa.eu/en/efsajournal/pub/2138.htm EFSA-Q-2011-00375 (in progress) EFSA-Q-2011-00376 (in progress) EFSA-Q-2011-00382 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus bulgaricus* = *L. delbrueckii* subsp. *bulgaricus*	Feed additive	EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/912.htm EFSA-Q-2010-00071 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus casei* (note: this species is very rare and its identity might need to be verified)	Feed additive	EFSA-Q-2011-00381(in progress) EFSA-Q-2011-00390 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus casei rhamnosus* = *Lactobacillus rhamnosus*	Feed additive	EFSA-Q-2011-00380 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus cellobiosus*	Feed additive		Not initially considered for QPS (see EFSA opinions 2007, 2008). QPS recommended 2009, 2010
FEEDAP	*Lactobacillus collinoides*	Feed additive		Not initially considered for QPS status (see EFSA opinions 2007, 2008). QPS recommended 2009, 2010
FEEDAP	*Lactobacillus delbrueckii subsp. lactis*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Lactobacillus farciminis*	Feed additive	EFSA-Q-2006-062 The EFSA Journal (2008) 771, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/771.htm EFSA-Q-2004-177 The EFSA Journal (2006) 377, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/377.htm	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus fermentum*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus helveticus*	Feed additive	EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/912.htm EFSA-Q-2010-00071 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus mucosae*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus paracasei*	Feed additive	EFSA-Q-2011-00378 (in progress) EFSA-Q-2011-00387 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus pentosus*	Feed additive	EFSA-Q-2011-00388 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus plantarum*	Feed additive	EFSA-Q-2010-01164 EFSA Journal 2011;9(3):2113 www.efsa.europa.eu/en/efsajournal/pub/2113.htm EFSA-Q-2011-00062 EFSA Journal 2011;9(6):2275 www.efsa.europa.eu/en/efsajournal/pub/2275.htm EFSA-Q-2011-00125 (in progress) EFSA-Q-2011-00186 (in progress) EFSA-Q-2011-00374 (in progress) EFSA-Q-2011-00377 (in progress) EFSA-Q-2011-00384 (in progress) EFSA-Q-2011-00390 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Lactobacillus reuteri*	Feed additive	EFSA-Q-2003-010 The EFSA Journal (2005) 229, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/229.htm EFSA-Q-2006-169 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus rhamnosus*	Feed additive	EFSA-Q-2006-062 The EFSA Journal (2008) 771, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/771.htm EFSA-Q-2011-00125 (in progress) EFSA-Q-2011-00380 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010) *Lactobacillus rhamnosus* is recommended for the QPS list, and remains a topic for surveillance.
FEEDAP	*Lactobacillus sakei*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus salivarius*	Feed additive	EFSA-Q-2006-169 (in progress) EFSA-Q-2009-00823 (In progress) EFSA-Q-2011-00381 (In progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactococcus lactis*	Feed additive	EFSA-Q-2006-135 www.efsa.europa.eu/en/efsajournal/pub/912.htm EFSA-Q-2010-00071 (in progress) EFSA-Q-2010-00901 (in progress) EFSA-Q-2011-00373 (in progress) EFSA-Q-2011-00383 (in progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010) Attention should be focused on human clinical cases without underlying predisposing factors (EFSA, 2011).
2001/122/EC	*Leuconostoc mesenteroides*	Production of dextran as NF ingredient for bakery industrial and food fermentations		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Leuconostoc oeno* = *Oenococcus oeni*	Feed additive		Not initially considered for QPS (see EFSA opinion 2007, 2008) and recommended for the QPS list in 2009, 2010 (EFSA, 2009; 2010)
FEEDAP	*Leuconostoc pseudomesenteroides*	Feed additive		Not recommended for QPS (see EFSA opinions 2007, Appendix A; 2009; 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Methylococcus capsulatus*	Biomass for animal feed	EFSA-Q-2004-171 The EFSA Journal (2005) 230, 1-6 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620784006.htm	No body of knowledge, therefore not appropriate for QPS (EFSA, 2008)
Opinion SCF adopted on 22/06/2000	*Paenibacillus macerans*	b-cyclodextrin production (food additive)		QPS 2009 update not recommended for QPS because of insufficient body of knowledge. It will no longer be assessed for the QPS list unless new notification to EFSA.
FEEDAP	Astaxanthin-rich *Paracoccus carotinifaciens*	Production of red carotenoids	EFSA-Q-2006-173 The EFSA Journal (2007) 546, 1-30 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178650355146.htm EFSA-Q-2009-00629 EFSA Journal 2010; 8(1):1428 [8 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1428.htm	No body of knowledge, therefore not considered for QPS (EFSA, 2008)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Pediococcus acidilactici*	Feed additive	EFSA-Q-2006-169 (in progress) EFSA-Q-2007-205 www.efsa.europa.eu/en/scdocs/scdoc/1037.htm EFSA-Q-2008-421 www.efsa.europa.eu/en/scdocs/scdoc/1038.htm EFSA-2009-00719 EFSA Journal 2010;8(7):1660 www.efsa.europa.eu/en/scdocs/scdoc/1660.htm EFSA-2009-00716 EFSA Journal 2010;8(10):1865 www.efsa.europa.eu/en/scdocs/scdoc/1865.htm EFSA-2009-00719 EFSA Journal 2010;8(7):1660 www.efsa.europa.eu/en/scdocs/scdoc/1660.htm EFSA-2009-00716 EFSA Journal 2010;8(10):1865 www.efsa.europa.eu/en/scdocs/scdoc/1865.htm EFSA-Q-2011-00379 (in progress)	Already QPS
FEEDAP	*Pediococcus pentosaceus*	Feed additive	EFSA-Q-2009-00717 EFSA Journal 2010; 8(2):1502 www.efsa.europa.eu/en/scdocs/scdoc/1502.htm EFSA-Q-2011-00386 (in progress)	Already QPS
FEEDAP	*Propionibacterium acidipropionici*	Feed additive	EFSA-Q-2011-00953 (in progress)	Not proposed for QPS status (see EFSA opinion 2007, Appendix A). In 2009, 2010 recommended for the QPS list (EFSA, 2009; 2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Propionibacterium freudenreichii shermanii*	Feed additive		Already QPS
FEEDAP	*Propionibacterium freudenreichii shermanii*	Production of vitamin B12	Formal mandate still to arrive	Already QPS
FEEDAP	*Propionibacterium globosum* [=subspecies of *Propionibacterium freudenreichii*]	Feed additive		Not recommended for QPS (see EFSA opinion 2007, Appendix A). Identical with *P. freudenreichii* therefore included on QPS (EFSA, 2010)
Pesticides	*Pseudomonas sp.* DSMZ 13134	Plant Protection Product	Draft Assessment Report: no further info on the species. It is considered as a new species within the RNA-group I-pseudomonads. No EFSA question number yet.	Not assessed because species to be clarified (EFSA, 2009)
Pesticides	*Pseudomonas chlororaphis*	Plant Protection Product	EFSA-Q-2008-618 [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_006478.htm]	Not recommended for QPS in QPS 2009 update because of insufficient body of knowledge and a potential risk linked to production of secondary metabolites. It will no longer be assessed for the QPS list unless new notification to EFSA.
FEEDAP	*Rhodopseudomonas palustris*	Feed additive		Insufficient body of knowledge (EFSA 2009). It will no longer be assessed for the QPS list unless new notification to EFSA.
FEEDAP	*Serratia rubidaea*	Feed additive		Insufficient body of knowledge (EFSA 2009). It will no longer be assessed for the QPS list unless new notification to EFSA.
FEEDAP	*Streptococcus cremoris = L. lactis subsp. cremoris*	Feed additive		Already QPS

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Streptococcus faecium* = *Enterococcus faecium*	Feed additive		No taxonomical unit within *Enterococcus* can be considered as free of infectious strains. Therefore no recommendation for QPS status (EFSA opinion, 2007, 2008, 2009, 2010). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Streptococcus thermophilus*	Feed additive	EFSA-Q-2006-135 www.efsa.europa.eu/en/scdocs/scdoc/912.htm EFSA-Q-2010-00071 (in progress)	Already QPS
FEEDAP	*Streptomyces albus*	Production of salinomycin sodium	EFSA-Q-2003-009 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783414.htm	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)
FEEDAP	*Streptomyces aureofaciens*	Production of polyether monocarboxylic acid	EFSA-Q-2003-046 The EFSA Journal (2004), 90, 1-44 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783396.htm	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)
FEEDAP	*Streptomyces cinnamonensis*	Production of monensin sodium	EFSA-Q-2005-024 The EFSA Journal (2004), 42, 1-61 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783743.htm	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)
Pesticides	Now unspecified *Streptomyces* species *:* '*Streptomyces* strain K 61' Formerly : *Streptomyces griseoviridis*	Plant protection product	EFSA-Q-2009-00134 (In progress) EFSA-Q-2009-00295 (in progress) [www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_129069.htm]	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion, 2008)
FEEDAP	*Streptomyces lasaliensis*	Production of lasalocid sodium	EFSA-Q-2004-076 The EFSA Journal (2004) 77, 1-45 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783432.htm	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Pesticides	*Streptomyces lydicus* strain WYEC 108 (ATCC 55445)	Plant protection product	No Draft Assessment Report received – no EFSA Question yet.	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008).
	Yeasts			
Pesticides	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Plant Protection Product	EFSA-Q-2010-01499 (in progress)	Body of knowledge insufficient (QPS 2009 update)
FEEDAP	*Candida glabrata*	Feed additive		Unsuitable for QPS (see EFSA opinion 2007, Appendix C)
FEEDAP	*Candida guilliermondi*	Fermentation product	EFSA-Q-2003-082 www.efsa.europa.eu/en/efsajournal/pub/68.htm	Unsuitable for QPS (see EFSA opinion 2007, Appendix C)
Pesticides	*Candida oleophila* strain O	Plant protection product	EFSA-Q-2009-00338 (in progress) [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_021008.htm]	Body of knowledge insufficient, therefore not appropriate for QPS (EFSA opinion 2008)
FEEDAP	*Hansenula polymorpha = Pichia angusta*	Production of enzymes	EFSA-Q-2005-030 The EFSA Journal (2006) 333, 1-27 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769671.htm	Already QPS status applies only when species is used for production purposes (EFSA opinion 2008, 2010)
2148/2004/EC	*Kluyveromyces marxianus var. lactisK1*	Feed additive		Already QPS
Reg(EC)773/2006 Corrigendum CS	*Kluyveromyces marxianus-fragilis*	Feed additive		Already QPS
FEEDAP	Astaxanthin rich *Phaffia rhodozyma = Xanthophyllomyces dendrorhous*	Production of astaxanthin	EFSA-Q-2004-148 The EFSA Journal (2004) 43, 1-4 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783707.htm EFSA-Q-2003-112 The EFSA Journal (2004) 43, 1-4 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783707.htm	*Phaffia rhodozyma* was assessed not appropriate for QPS (EFSA opinion 2008) because of insufficient body of knowledge. Later recommended for the QPS list (EFSA, 2011) as it is the imperfect form of *Xanthophyllomyces dendrorhous* according to the 2011 revision of the yeast taxonomy.

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Komagaella pastoris* = *Pichia pastoris*	Production of Enzyme	EFSA-Q_2006-025 (GMM) www.efsa.europa.eu/en/efsajournal/pub/627.htm and related opinions: EFSA-Q-2009-00804: www.efsa.europa.eu/en/efsajournal/pub/1550.htm EFSA-Q-2010-00152 (GMM, additional data request) EFSA-Q-2011-00148 (in progress) Other applications: EFSA-Q-2010-00152 (GMM, in progress)	
FEEDAP	*Saccharomyces cerevisiae*	Organic selenium source	EFSA-Q-2005-071 www.efsa.europa.eu/en/efsajournal/pub/348.htm EFSA-Q-2005-117 www.efsa.europa.eu/en/efsajournal/pub/430.htm EFSA-Q-2008-381 www.efsa.europa.eu/en/efsajournal/pub/992.htm EFSA-Q-2009-00524 EFSA Journal 2011;9(6):2279 www.efsa.europa.eu/en/efsajournal/pub/2279.htm EFSA-Q-2009-00752 EFSA Journal 2011;9(4):2110 www.efsa.europa.eu/en/efsajournal/pub/2110.htm EFSA-Q-2010-01029 (in progress)	
FEEDAP	*Saccharomyces cerevisiae*	Production of Enzyme	EFSA-Q-2005-224 and EFSA-Q-2009-00534 (GMM, in progress)	
FEEDAP	*Saccharomyces cerevisiae*	Feed additive	EFSA-Q-2005-025 www.efsa.europa.eu/en/efsajournal/pub/384.htm	Already QPS (EFSA Opinions 2007, 2008, 2009, 2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
			EFSA-Q-2005-234 The EFSA Journal (2006) 385, 1-9 www.efsa.europa.eu/en/scdocs/scdoc/385.htm EFSA-Q-2005-149 The EFSA Journal (2006) 321, 1-8 www.efsa.europa.eu/en/scdocs/scdoc/321.htm EFSA-Q-2005-176 www.efsa.europa.eu/en/efsajournal/pub/370.htm EFSA-Q-2006-003 www.efsa.europa.eu/en/efsajournal/pub/379.htm EFSA-Q-2006-067 www.efsa.europa.eu/en/efsajournal/pub/459.htm EFSA-Q-2007-104 www.efsa.europa.eu/en/efsajournal/pub/585.htm EFSA-Q-2007-139 The EFSA Journal (2008) 772, 1-11 www.efsa.europa.eu/en/scdocs/scdoc/772.htm EFSA-Q-2007-165 EFSA Journal 2009; 7(10):1353 www.efsa.europa.eu/en/scdocs/scdoc/1353.htm EFSA-Q-2008-009 The EFSA Journal (2009) 991, 1-14 www.efsa.europa.eu/en/scdocs/scdoc/991.htm EFSA-Q-2008-010 The EFSA Journal (2008) 837, 1-10 www.efsa.europa.eu/en/scdocs/scdoc/837.htm	

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
			EFSA-Q-2008-302 The EFSA Journal (2009) 970, 1-9 www.efsa.europa.eu/en/scdocs/scdoc/970.htm EFSA-Q-2008-472 The EFSA Journal (2009) 1040, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/1040.htm EFSA-Q-2009-00720 EFSA Journal 2010;8(10):1864 www.efsa.europa.eu/en/scdocs/scdoc/1864.htm EFSA-Q-2009-00753 EFSA Journal 2010;8(7):1659 www.efsa.europa.eu/en/scdocs/scdoc/1662.htm EFSA-Q-2009-00818 (In progress) EFSA-Q-2009-00824 EFSA Journal 2010;8(7):1662 www.efsa.europa.eu/en/scdocs/scdoc/1662.htm EFSA-Q-2010-00938 (in progress) EFSA-Q-2010-00936 (in progress) EFSA-Q-2010-00992 www.efsa.europa.eu/en/efsajournal/pub/2173.htm EFSA-Q-2011-00390 (in progress)	
GMO	*Saccharomyces cerevisiae*	Dried killed biomass for feed	EFSA-Q-2007-156b (under consideration) EFSA-Q-2009-00866 (Waiting for full dossier)	

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Schizosaccharomyces pombe*	Production of enzymes	EFSA-Q-2005-063 The EFSA Journal (2006) 350, 1-14 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769568.htm EFSA-Q-2005-080 The EFSA Journal (2006) 404, 1-20 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620782208.htm EFSA-Q-2008-272 The EFSA Journal (2006) 350, 1-14 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769568.htm EFSA-Q-2011-00835 (in progress)	Already QPS (EFSA Opinions 2007, 2008, 2009, 2010).
	Fungi			
Pesticides	*Ampelomyces quisqualis*	Plant protection product	EFSA-Q-2008-489 (in progress)	Not recommended for the QPS list, QPS 2011 update
FEEDAP	*Ashbya gossypii*	Production of vitamin B2	Formal mandate still to arrive (GMM)	Not recommended for the QPS list, QPS 2011 update
FEEDAP	*Aspergillus aculeatus*	Production of Enzyme	EFSA-Q-2008-432: www.efsa.europa.eu/en/efsajournal/pub/1186.htm EFSA-Q-2011-00035: www.efsa.europa.eu/en/efsajournal/pub/2010.htm EFSA-Q-2010-01297 (in progress) EFSA-Q-2010-01295(in progress)	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
FEEDAP	*Aspergillus niger*	Feed additive	EFSA-Q-2009-00585 (in progress) EFSA-Q-2009-00534 (in progress)	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Aspergillus niger*	Production of Enzyme	EFSA-Q-2004-068 (GMM) www.efsa.europa.eu/en/efsajournal/pub/198.htm and related opinions: EFSA-Q-2006-119 www.efsa.europa.eu/en/efsajournal/pub/474.htm EFSA-Q-2008-418 www.efsa.europa.eu/en/efsajournal/pub/1155.htm EFSA-Q-2011-00147 (in progress) EFSA-Q-2005-116 (GMM) The EFSA Journal (2006) 369, 1-19 www.efsa.europa.eu/en/efsajournal/doc/369.pdf and related opinions: EFSA-Q-2007-049: www.efsa.europa.eu/en/efsajournal/pub/472.htm EFSA-Q-2007-041: www.efsa.europa.eu/en/efsajournal/pub/544.htm EFSA-Q-2007-189: www.efsa.europa.eu/en/efsajournal/pub/614.htm EFSA-Q-2008-692: www.efsa.europa.eu/en/efsajournal/pub/1184.htm EFSA-Q-2009-00603: www.efsa.europa.eu/en/efsajournal/pub/1427.htm EFSA-Q-2008-013 (GMM) www.efsa.europa.eu/en/efsajournal/pub/914.htm and related Questions: EFSA-Q-2010-00937 EFSA Journal 2011;9(5):2172 www.efsa.europa.eu/en/efsajournal/pub/2172.htm EFSA-Q-2010-01519 (in progress) FAD-2010-0367 (formal mandate to arrive) EFSA-Q-2011-00061 (in progress)	

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Aspergillus oryzae*	Production of Enzymes	EFSA-Q-2003-012 (GMM): www.efsa.europa.eu/en/efsajournal/pub/66.htm and related opinions: EFSA-Q-2004-070: www.efsa.europa.eu/en/efsajournal/pub/88.htm EFSA-Q-2006-060: www.efsa.europa.eu/en/efsajournal/pub/519.htm EFSA-Q-2007-132: www.efsa.europa.eu/en/efsajournal/pub/132.htm EFSA-Q-2009-00535: www.efsa.europa.eu/en/efsajournal/pub/535.htm EFSA-Q-2007-133 (GMM): www.efsa.europa.eu/en/efsajournal/pub/871.htm and related opinions: EFSA-Q-2008-430: www.efsa.europa.eu/en/efsajournal/pub/1097.htm EFSA-Q-2009-00536: www.efsa.europa.eu/en/efsajournal/pub/1634.htm EFSA-Q-2008-419 (GMM, in progress) EFSA-Q-2010-00769 (in progress) EFSA-Q-2010-01519 (GMM, in progress)	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
FEEDAP	*Aspergillus oryzae*	Feed additive	EFSA-Q-2009-00525 (in progress)	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
Pesticides	*Beauveria bassiana* (ATCC-74040 and GHA)	Plant protection product	EFSA-Q-2009-00125 (in progress) EFSA-Q-2009-00251 (in progress) [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_128818.htm www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_128924.htm]	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Pesticides	*Beauveria brongniartii*	Plant protection product	EFSA-Q-2009-00017 (in progress)	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge, potential oosporein formation (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
ACF (as mentioned in the register of questions)	*Blakeslea trispora*	Production of lycopene (food colorant) Production of b-carotene (food colorant)	EFSA-Q-2004-102 The EFSA Journal (2005) 275, 1-17 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620764493.htm EFSA-Q-2007-001 The EFSA Journal (2008) 674, 1-66 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178700117557.htm	Can not be proposed for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
FEEDAP	*Blakeslea trispora*	Production strain for beta-carotene	EFSA-Q-2009-00884 (in progress)	QPS 2009, 2010 update
NDA	*Blakeslea trispora*	Food ingredient	EFSA-Q-2004-169 The EFSA Journal (2005) 212, 1-29 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620765774.htm EFSA-Q-2008-697 The EFSA Journal (2008) 893, 1-15 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902228574.htm	QPS 2009, 2010 update
Pesticides	*Coniothyrium minitans*	Plant protection product	EFSA-Q-2008-515 (in progress) [Review report for the active substance *Coniotyrium minitans*, SANCO/1400/2001-final, July 2003] [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_028836.htm]	The body of knowledge is insufficient. Potential acrosphelide formation (EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Duddingtonia flagrans* Alternative name: *Trichothecium flagrans*	Feed additive	EFSA-Q-2004-115 The EFSA Journal (2006) 334, 1-8 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783270.htm EFSA-Q-2005-051 under consideration	Insufficient body of knowledge (EFSA, 2009; EFSA, 2010)
Pesticides	*Gliocladium catenulatum* = *Clonostachys rosea* forma *catenulata* strain J1446	Plant protection product	EFSA-Q-2008-559 (in progress) [www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_021009.htm]	No recommendation for QPS in 2009 (EFSA, 2009). No new relevant information in the 2010 update.
Pesticides	*Lecanicillium muscarium* *Formerly Verticillium lecanii* strain Ve6	Plant protection product	EFSA-Q-2009-00130 (in progress) EFSA-Q-2009-00255 (finalized on 18/12/2009) Conclusion on the peer review (2009): www.efsa.europa.eu/en/scdocs/scdoc/1446.htm	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Metarhizium anisopliae* var. Anisopliae formerly *M. anisopliae*	Plant protection product	EFSA-Q-2009-00131 (in progress) EFSA-Q-2009-00253 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Paecilomyces fumosoroseus* strain FE 9901 (ARSEF 4490)	Plant protection product	EFSA-Q-2008-599 (in progress) EFSA-Q-2009-00323 (in progress) [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_115002.htm]	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
FEEDAP	*Penicillium funiculosum*	Production of Enzyme	EFSA-Q-2005-281 (GMM) www.efsa.europa.eu/en/efsajournal/pub/471.htm EFSA-Q-2010-01287 in progress) EFSA-Q-2011-0026 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Paecilomyces lilacinus* strain 251	Plant protection product	EFSA-Q-2008-600 (finalized on 13/06/2007) Conclusion on the peer review (2007): www.efsa.europa.eu/en/scdocs/scdoc/103r.htm [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_028826.htm]	Mycelial fungi: already considered as not appropriate for QPS. Potential for production of peptaibols (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Pesticides	*Phlebiopsis gigantean* 14 different strains	Plant protection product	EFSA-Q-2009-00132 (in progress) EFSA-Q-2009-00285 (in progress)	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Pseudozyma flocculosa* strain ATCC 64874	Plant protection product	EFSA-Q-2009-00315 (in progress) [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_119196.htm]	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Pythium oligandrum* M1	Plant protection product	EFSA-Q-2009-00133 (in progress) EFSA-Q-2009-00287 (in progress) [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_028816.htm]	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma asperellum* strain T-34	Plant protection product	EFSA-Q-2011-00899	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma asperellum* strains ICC 012, T11 and TV1	Plant protection product	EFSA-Q-2009-00136 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma atroviride* I-1237	Plant protection product	EFSA-Q-2011-00900	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma atroviride IMI 206040* and T11	Plant protection product	EFSA-Q-2009-00137 (in progress) EFSA-Q-2009-00297 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma harzianum Rifai* (strains T22 and ITEM 908)	Plant protection product	EFSA-Q-2009-00139 (in progress) EFSA-Q-2009-00298 (in progress) [www.epa.gov/opp00001/biopesticides/ ingredients/factsheets/factsheet_128902.htm]	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
FEEDAP	*Trichoderma longibrachiatum*	Feed additive		Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Trichoderma longibrachiatum*	Production of Enzyme	EFSA-Q-2005-276 www.efsa.europa.eu/en/efsajournal/pub/405.htm and related opinion: EFSA-Q-2006-320: www.efsa.europa.eu/en/efsajournal/pub/520.htm EFSA-Q-2008-288 (in progress) EFSA-Q-2010-00036 (in progress) EFSA-Q-2010-01025 (in progress) EFSA-Q-2010-01295 (in progress) EFSA-Q-2010-01297 (in progress) FAD-2010-0367 (formal mandate to arrive)	Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma polysporum* strain IMI 206039	Plant protection product	EFSA-Q-2009-00140 (in progress) EFSA-Q-2009-00299 (in progress) [www.epa.gov/opp00001/biopesticides/ ingredients/factsheets/factsheet_128902.htm]	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Trichoderma reesei*	Production of enzyme	EFSA-Q-2006-137 (GMM) www.efsa.europa.eu/en/efsajournal/pub/548.htm and related opinions: EFSA-Q-2007-0020: www.efsa.europa.eu/en/efsajournal/pub/1156.htm EFSA-Q-2007-109: www.efsa.europa.eu/en/efsajournal/pub/586.htm EFSA-Q-2007-112: www.efsa.europa.eu/en/efsajournal/pub/1154.htm EFSA-Q-2007-185 (in progress) EFSA-Q-2009-00470: www.efsa.europa.eu/en/efsajournal/pub/1949.htm EFSA-Q-2010-00141: www.efsa.europa.eu/en/efsajournal/pub/1916.htm EFSA-Q-2009-00802: EFSA Journal 2011;9(2):2008 www.efsa.europa.eu/en/efsajournal/pub/2008.htm EFSA-Q-2007-120 (GMM) www.efsa.europa.eu/en/efsajournal/pub/712.htm and related question: EFSA-Q-2010-00142 (additional data request) EFSA-Q-2010-00142 EFSA Journal 2011;9(6):2277 www.efsa.europa.eu/en/efsajournal/pub/2277.htm	Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Trichoderma reesei*	Production of enzyme	EFSA-Q-2008-308: www.efsa.europa.eu/en/efsajournal/pub/1094.htm and related questions: EFSA-Q-2010-00018 (additional data request) EFSA-Q-2008-432: www.efsa.europa.eu/en/efsajournal/pub/1186.htm EFSA-Q-2008-748 (GMM): www.efsa.europa.eu/en/efsajournal/pub/1380.htm and related opinon: EFSA-Q-2010-0069 www.efsa.europa.eu/en/efsajournal/pub/1553.htm EFSA-Q-2011-00112 www.efsa.europa.eu/en/efsajournal/pub/2111.htm EFSA-Q-2010-00141: www.efsa.europa.eu/en/efsajournal/pub/1916.htm EFSA-Q-2010-00700: www.efsa.europa.eu/en/efsajournal/pub/1919.htm EFSA-Q_2011-00035: www.efsa.europa.eu/en/efsajournal/pub/2010.htm EFSA-Q-2011-00804 (in progress)	Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
FEEDAP	*Trichoderma viride*	Production of enzyme	EFSA-Q-2010-01295 (in progress) EFSA-Q-2010-01297 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma viride* =*Trichoderma gamsii* strains ICC 080, T25 and TV1	Plant protection product	EFSA-Q-2009-00138 (in progress) EFSA-Q-2009-00300 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Pesticides	*Verticillium albo-atrum* formerly *Verticillium dahliae*	Plant protection product	EFSA-Q-2009-00141 (in progress) EFSA-Q-2009-00303 (in progress)	Mycelial fungi: already considered as not appropriate for QPS. Potential production of alboatrin (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
FEEDAP	*Trichosporon mycotoxinivorans*	Feed additive	EFSA-Q-2010-01030 (The application has been withdrawn)	Not recommended for the QPS list, assessed in the current 2011 update
	Algae			
FEEDAP	*Haematococcus pluvialis*	Production of astaxanthin		No body of knowledge except for this strain. Therefore not considered for QPS (EFSA opinion 2008)
	Bacteriophages			
FEEDAP	*Clostridium sporogenes* phage	Feed additive		QPS 2009, 2010 updates
FEEDAP	*Clostridium tyrobutyricum* phage	Feed additive		QPS 2009, 2010 updates
	Viruses			
Pesticides	*Adoxophyes orana Granulovirus* strain BV-0001	Plant protection product	EFSA-Q-2009-00324 (in progress)	QPS 2009, 2010 update
Pesticides	*Cydia pomonella granulovirus* Mexican isolate	Plant protection product	EFSA-Q-2009-00126 (in progress) EFSA-Q-2009-00254 (in progress) [www.epa.gov/opp00001/biopesticides/ ingredients/factsheets/factsheet_107300.htm]	QPS 2009, 2010 update
Pesticides	*Helicoverpa armigera nucleopolyhedrovirus*	Plant protection product	EFSA-Q-2009-00341 (in progress)	QPS 2009, 2010 update
Pesticides	Spodoptera exigua nuclear polyhedrosis virus	Plant protection product	EFSA-Q-2008-630 (in progress)	QPS 2009, 2010 update
Pesticides	Spodoptera littoralis nucleopolyhedrovirus	Plant protection product	EFSA-Q-2009-00507 (in progress)	QPS 2009, 2010 update
Pesticides	Zucchini yellow mosaic virus, weak strain	Plant protection product	EFSA-Q-2009-00346 (in progress) [www.epa.gov/opp00001/biopesticides/ ingredients/factsheets/factsheet_244201.htm]	QPS 2009, 2010 update

Glossary

Yeast Synonyms commonly used in the feed/food industry

Wickerhamomyces anomalus: synonym *Hansenula anomala, Pichia anomola, Saccharomyces anomalus*
Pichia jadinii: anamorph *Candida utilis*; synonyms *Hansenula jadinii, Torulopsis utilis*
Saccharomyces cerevisiae synonym *S. boulardii*
Saccharomyces pastorianus: synonym of Saccharomyces carlsbergensis
Komagataella pastoris: synonym *Pichia pastoris*

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EFSA 2009 Opinion: Scientific Opinion on the maintenance of the list of QPS microorganisms intentionally added to food or feed (2009 update) (Question number: EFSA-Q-2009-00459) EFSA Journal 2009, 7, 12, 1431 www.efsa.europa.eu/en/scdocs/scdoc/1431.htm

EFSA, 2010 Panel on Biological Hazards (BIOHAZ) Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food or feed (2010 update). EFSA J. 8(12), 1944 [56 pp.] doi:10.2903/j.efsa.2010.1944. Available online: www.efsa.europa.eu/efsajournal.htm